



FEDERAL TRADE COMMISSION

16 CFR Part 456

RIN 3084-AB37

Ophthalmic Practice Rules (Eyeglass Rule)

AGENCY: Federal Trade Commission.

ACTION: Notice of proposed rulemaking; request for public comment.

SUMMARY: The Federal Trade Commission (“FTC” or “Commission”) proposes to amend the Ophthalmic Practice Rules (“Eyeglass Rule” or “Rule”) to require that prescribers obtain a signed confirmation after releasing an eyeglass prescription to a patient, and maintain each such confirmation for a period of not less than three years. The Commission also proposes to permit prescribers to comply with automatic prescription release via electronic delivery in certain circumstances. The Commission further proposes a clarification that the presentation of proof of insurance coverage shall be deemed to be a payment for the purpose of determining when a prescription must be provided. Finally, the Commission proposes to amend the term “eye examination” to “refractive eye examination” throughout the Rule. The Commission seeks comment on these proposals.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY**

INFORMATION section below. Write “Eyeglass Rule, Project No. R511996” on your comment, and file your comment through <https://www.regulations.gov>. If you prefer to file your comment on paper, write “Eyeglass Rule, Project No. R511996” on your comment and on the envelope and mail your comment to the following address: Federal

Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex C), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Alys Bernstein, Attorney, (202) 326-3289, Paul Spelman, Attorney, (202) 326-2487, or Sarah Botha, Attorney, (202) 326-2036, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: The Commission finds that using the procedures set forth in this notice of proposed rulemaking will serve the public interest by supporting the Commission's goals of clarifying and updating existing regulations without undue expenditure of resources, while ensuring that the public has an opportunity to submit data, views, and arguments on whether the Commission should amend the Rule. The Commission, therefore, has determined, pursuant to 16 CFR 1.20, to use the following procedures: (1) publishing this notice of proposed rulemaking; (2) soliciting written comments on the Commission's proposals to amend the Rule; (3) holding a workshop; and (4) announcing final Commission action in a document to be published in the *Federal Register*.

The Commission will host a workshop to gather additional public input regarding the proposed changes. After publishing this notice of proposed rulemaking ("NPRM"), the Commission will publish a document in the Federal Register announcing the workshop and providing instructions on how interested persons may request an opportunity to participate.

The Commission, in its discretion, has not chosen to schedule an informal hearing and has not made any initial designations of disputed issues of material fact necessary to be resolved at an informal hearing. The Commission believes that a workshop will provide sufficient opportunity for obtaining additional public input on its proposal. Interested persons who wish to make an oral submission at an informal hearing must file

a comment in response to this NPRM and submit a statement identifying their interests in the proceeding and describing any proposals regarding the designation of disputed issues of material fact to be resolved at the informal hearing, on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 16 CFR

1.11. Such requests, and any other motions or petitions in connection with this proceeding must be filed with the Secretary of the Commission.

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I. Background

A. Overview of the Eyeglass Rule

The Eyeglass Rule declares it an unfair practice for an optometrist or ophthalmologist to fail to provide a patient with a copy of the patient's eyeglass

prescription immediately after an eye examination is completed.¹ The prescriber may not charge the patient any fee in addition to the prescriber's examination fee as a condition to releasing the prescription to the patient.² The Rule defines a prescription as the written specifications for lenses for eyeglasses which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses.³

The Rule prohibits an optometrist or ophthalmologist from conditioning the availability of an eye examination on a requirement that the patient agree to purchase ophthalmic goods from the ophthalmologist or optometrist.⁴ The Rule also deems it an unfair act or practice for the prescriber to place on the prescription, or require the patient to sign, or deliver to the patient, a waiver or disclaimer of prescriber liability or responsibility for the accuracy of the exam or the ophthalmic goods and services dispensed by another seller.⁵

B. History of the Rule

The FTC has decades of regulatory and research experience with the optical goods industry, which continues to inform the basis and purpose of the Rule and this NPRM. The Commission's engagement in the industry predates formal adoption of the Eyeglass Rule. In 1962, the Commission first took steps to protect consumers and foster

¹ 16 CFR 456.2(a). A prescriber may withhold a patient's prescription until the patient has paid for the eye examination, but only if the prescriber would have required immediate payment if the examination had revealed that no ophthalmic goods were needed. *Id.*

² 16 CFR 456.2(c).

³ 16 CFR 456.1(g).

⁴ 16 CFR 456.2(b). The Rule thereby also prohibits conditioning the release of the prescription on the requirement that the patient purchase ophthalmic goods from the ophthalmologist or optometrist.

⁵ 16 CFR 456.2(d).

competition in the sale of eyeglasses by adopting the “Guides for the Optical Products Industry,” which included a provision declaring it an unfair trade practice to “tie in or condition” refraction services to the dispensing of eyeglasses when such a practice has a “reasonable probability” of harming competition.⁶ Among the conduct considered unfair were charging a higher or additional fee if the patient wanted to take the prescription elsewhere to buy eyeglasses, and refusing to perform examinations if the patient wanted to take the prescription elsewhere.⁷ The Guides were not binding, however, and the FTC never undertook litigation to enforce them,⁸ even though prescribers routinely violated the directives.⁹

1. Eyeglass I Report and Rule

On September 16, 1975, the Commission directed its staff to examine the retail ophthalmic market, including whether prescribers were tying eyeglass dispensing to examination, and whether such practices harmed consumers.¹⁰ Staff surveyed state laws and regulations, and solicited comment from a variety of interested parties, including ophthalmic licensing boards, professional associations, and consumer groups.¹¹ The

⁶ 16 CFR 192 (rescinded); *see also* “Staff Report on Advertising of Ophthalmic Goods and Services and Proposed Trade Regulation Rule,” 235-36 (1977), <https://www.ftc.gov/reports/staff-report-advertising-ophthalmic-goods-services-proposed-trade-regulation-rule-16-cfr-part-456?msclkid=957f749bc63711ecaefb4944debc75db> [hereinafter Eyeglass I Report].

⁷ Eyeglass I Report, *supra* note 6, at 235-36.

⁸ *Id.*

⁹ *See id.* at 240-48 (detailing myriad accounts of prescribers refusing to release eyeglass prescriptions to their patients); *see also* Final Trade Regulation Rule, Advertising of Ophthalmic Goods and Services, 43 FR 23992, 23998 (June 2, 1978) [hereinafter Eyeglass I Rule] (finding that in nearly every survey of practicing optometrists considered in the rulemaking record, more than 50 percent imposed a restriction on the availability of eyeglass prescriptions to patients).

¹⁰ Eyeglass I Report, *supra* note 6, at 1.

¹¹ *Id.*

Commission then sought comment on a proposed rule to eliminate certain advertising restraints on ophthalmic goods and services, and indicated that if evidence showed that consumers were being prevented from price shopping—due to the unavailability of prescriptions—the Commission might require prescribers to give patients copies.¹²

FTC staff subsequently released its Eyeglass I Report detailing practices that prescribers used to discourage consumers from taking prescriptions to be filled elsewhere, including (1) outright refusal to release prescriptions or refusal to conduct examinations unless the patient agreed to purchase eyeglasses; (2) charging an additional fee as a condition to releasing the prescription; and (3) conditioning the release of the prescription on the patient signing a release or waiver of liability.¹³ Staff explained that significant evidence—including testimony from optometrists, patients, and consumer groups, as well as prescriber surveys and published statements from boards of optometry and opticians—established that such practices were a serious and pervasive problem.¹⁴ The Report concluded that refusal to release prescriptions, or placing conditions on their release, constituted an unfair act or practice, and recommended that the Commission promulgate a rule “insuring consumers unconditional access to their ophthalmic prescriptions.”¹⁵

On June 2, 1978, the Commission issued the Advertising of Ophthalmic Goods and Services Rule (the “Eyeglass I Rule”), which, among other things, contained a provision titled “Separation of Examination and Dispensing” requiring prescribers to

¹² *Id.*

¹³ *Id.* at 241. With respect to liability waivers and releases, the Eyeglass I Report concluded that there could be “little doubt” that their primary intent was to discourage or dissuade consumers from taking their eyeglass prescriptions elsewhere to be filled. *Id.* at 277.

¹⁴ *Id.* at 241-45, 252-54.

¹⁵ *Id.* at 259, 263-65.

automatically release prescriptions to their patients—regardless of whether or not the patients requested them—to ensure consumers unconditional access to their prescriptions so they could comparison-shop for eyeglasses.¹⁶ In the Rule’s Statement of Basis and Purpose, the Commission explained that evidence conclusively established that consumers suffered substantial economic loss through the imposition of surcharges for obtaining their prescriptions, and through lost opportunity costs arising from an inability to comparison-shop for eyeglasses.¹⁷ Furthermore, the Commission found that prescribers’ use of waiver notices and disclaimers deceived consumers as to the capabilities of other optical dispensaries, and further restricted purchase options.¹⁸ Such practices offended public policy in that they denied consumers the ability to effectively use available information, and inhibited competition in retail eyeglasses markets.¹⁹

The Commission added that while it considered only requiring prescription release upon consumer request, it opted instead for so-called “automatic release” due to consumers’ lack of awareness that they could purchase eyeglasses elsewhere, and because absent automatic release, there might be “evidentiary squabbles” over whether consumers did or did not request their prescription.²⁰ In addition, the Commission noted there was no evidence to suggest automatic release would impose a significant burden on prescribers.²¹

¹⁶ Eyeglass I Rule, 43 FR 23992, 23998, 24007-08.

¹⁷ *Id.* at 24003.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.* at 23998.

²¹ *Id.*

After issuance of the Eyeglass I Rule, the American Optometric Association (“AOA”), representing most of the country’s optometrists, challenged it, and in 1980 the D.C. Circuit overturned Rule provisions pertaining to advertising restrictions.²² The court, however, upheld the automatic prescription release requirement, finding there was ample evidence that withholding prescriptions harmed consumers by making comparison-shopping harder, removing incentives for ophthalmic goods sellers to advertise, and reducing opticians’ ability to compete.²³ The court also noted there was considerable evidence that prescribers had used waivers and liability disclaimers “to discourage comparison shopping, to mislead consumers..., and to frighten consumers into purchasing ophthalmic goods and services” from the prescriber.²⁴

2. Eyeglass II Report and Rule

Following the court’s remand of the Eyeglass I Rule, FTC staff conducted further investigation, and in 1980 issued a staff report entitled “State Restrictions on Vision Care Providers: The Effects on Consumers (“1980 Staff Report”).²⁵ The 1980 Staff Report did not make recommendations regarding the automatic prescription release provision, but instead suggested the Commission seek comment on whether to change it to release upon request, or to sunset the release requirement altogether.²⁶

²² *Am. Optometric Ass’n v. FTC*, 626 F.2d 896, 910-11 (D.C. Cir. 1980).

²³ *Am. Optometric Ass’n*, 626 F.2d at 915.

²⁴ *Id.* at 916.

²⁵ “State Restrictions on Vision Care Providers: The Effects on Consumers” (1980), <https://www.ftc.gov/reports/state-restrictions-vision-care-providers-effects-consumers-eyeglasses-ii>

²⁶ *Id.* at 248-49. The 1980 Staff Report, however, did propose extending the automatic release requirement to cover eyeglass dispensers, so that opticians—as well as optometrists and other eyeglass dispensers—would be required to return prescriptions to patients after fabricating the eyeglasses. *Id.* at 133, 260-61. The aim of staff’s proposal was to guarantee patients access to their prescriptions even after they had been filled, and to ensure that consumers retained a copy so they could obtain duplicate glasses later

Following the 1980 Staff Report, the Commission sponsored a survey to determine to what extent prescribers were complying with the Rule. The survey, commonly known as the “Market Facts Study,” found that only about one-third of prescribers automatically provided patients with prescriptions.²⁷ Thus, the majority of prescribers were not in compliance. The survey also found that only 38 percent of consumers knew they were entitled to receive their prescription automatically.²⁸ The survey found, however, that when consumers requested their prescriptions, by and large prescribers no longer refused to release them,²⁹ and that a majority of consumers had become “generally knowledgeable” about the availability of eyeglass prescriptions, appearing to know they could request one.³⁰

Five years later, the Commission again reviewed the Rule and sought comment on whether consumers were aware of their right to obtain their prescription,³¹ and whether the automatic release provision ought to be terminated, changed to release upon request, or changed to require that prescribers simply “offer” patients their prescriptions rather

without having to return to their original prescriber or eyeglass dispenser. *Id.* at 134, 261-64. Staff later reversed course on this proposal, however, after determining that there was insufficient evidence that dispensers were refusing to return prescriptions to patients. The Commission chose not to adopt the proposal. *See* “Ophthalmic Practice Rules: State Restrictions on Commercial Practice,” 250, 300-02 (1986), <https://www.ftc.gov/reports/ophthalmic-practice-rules-state-restrictions-commercial-practice-eyeglasses-ii-report-staff> [hereinafter Eyeglass II Report]; Final Trade Regulation Rule, Ophthalmic Practice Rules, 54 FR 10285, 10303 (Mar. 13, 1989) [hereinafter Eyeglass II Rule].

²⁷ Eyeglass II Report, *supra* note 26, at 256.

²⁸ *Id.* at 258. Forty-six percent wrongly believed they were entitled to the prescription only upon request, and 18 percent wrongly believed that prescribers were permitted to charge extra if the patient asked for the prescription. *Id.*

²⁹ *Id.* at 253-62.

³⁰ *Id.*

³¹ Ophthalmic Practice Rules, Notice of Proposed Rulemaking, 50 FR 598, 602 (Jan. 4, 1985).

than automatically provide them.³² After public hearings, the hearing officer issued a report to the Commission (“Presiding Officer’s Report”)³³ finding that, although most prescribers would release prescriptions upon request, many were still not releasing them automatically. Accordingly, the presiding officer recommended that the automatic release requirement not be modified or terminated.³⁴

In contrast, FTC staff issued its own report (“Eyeglass II Report”), which proposed changing the release provision from automatic release to release upon request.³⁵ Staff based its proposal on what it perceived to be altered market conditions and increased consumer awareness, as well as the difficulty staff had encountered enforcing the automatic release provision.³⁶ According to staff, the automatic release requirement had not succeeded at “avoiding evidentiary squabbles,”³⁷ but rather had increased them, since whether a prescriber had released a prescription could not, in most cases, be ascertained by documentary evidence.³⁸

Despite staff’s recommendation, the Commission, in its final rule—referred to as the “Eyeglass II Rule”—sided with the Presiding Officer and opted to retain the

³² The Commission received significant comment and evidence on whether to maintain automatic prescription release, repeal it, or change it to release upon request, but very little comment or evidence regarding the option of offering patients prescriptions. Eyeglass II Rule, 54 FR 10285, 10303 & n.182.

³³ Report of the Presiding Officer on Proposed Regulation Rule: Ophthalmic Practice Rules, Public Record No. 215-63 (May 1, 1986), <https://www.ftc.gov/reports/report-presiding-officer-proposed-trade-regulation-rule-ophthalmic-practice-rules-eyeglass-rule-16?msclkid=c8131b8ac63911ecb89f5b16ef81c791>.

³⁴ *Id.*

³⁵ Eyeglass II Report, *supra* note 26, at 249.

³⁶ *Id.* at 249, 274-276.

³⁷ Eyeglass I Rule, 43 FR 23992, 23998.

³⁸ Eyeglass II Report, *supra* note 26, at 275-76.

automatic release component.³⁹ As the basis for its decision, the Commission cited the comments and testimony about continued prescriber non-compliance,⁴⁰ as well as the Market Facts Study and findings of the Presiding Officer, which established that many prescribers were not automatically providing prescriptions as required.⁴¹ The Commission also cited an additional survey submitted by the American Association of Retired Persons (“AARP”), which found significant non-compliance and lack of consumer awareness, particularly among older consumers.⁴²

The Eyeglass II Rule was again challenged by the optometric industry and, in 1990, much of the Rule was vacated, but not the prescription release requirements, which remained in effect.⁴³

3. The 1997 to 2004 Eyeglass Rule Review

In 1997, as part of its systematic review of its rules and regulations, the Commission again requested comment on whether the Rule’s prescription release requirement should be retained, modified, or eliminated.⁴⁴ The Commission received

³⁹ Eyeglass II Rule, 54 FR 10285, 10286-87.

⁴⁰ *Id.* at 10303.

⁴¹ *Id.* at 10313 & nn.180 & 181; *see also* Eyeglass II Report, *supra* note 26, at 255-58 (reporting the Market Facts Study results).

⁴² Eyeglass II Rule, 54 FR 10285, 10303 nn.180 & 181; *see also* Eyeglass II Report, *supra* note 26, at 263 (reporting that the AARP survey of older Americans found that 47 percent did not receive a copy of their prescription, and 32 percent of those did not know to ask for one).

⁴³ *See Cal. State Bd. of Optometry v. FTC*, 910 F.2d 976 (D.C. Cir. 1990). The decision focused on a determination that the FTC lacked statutory authority to declare state laws of optometry to be unfair acts or practices without more explicit authority from Congress. Following the court decision, the Commission, in 1992, reissued the Eyeglass Rule, but without the portions declared invalid, and with renumbered designations pertaining to prescription release. *See* Final Trade Regulation Rule, Ophthalmic Practice Rules, 57 FR 18822 (May 1, 1992).

⁴⁴ Ophthalmic Practice Rules, Request for Comments, 62 FR 15865, 15867 (Apr. 3, 1997).

comments from numerous parties but withheld taking action while it considered whether contact lenses should be covered by the Rule. Ultimately, after Congress passed the Fairness to Contact Lens Consumers Act (“FCLCA”),⁴⁵ the Commission issued a separate Contact Lens Rule (“CLR”) with prescription release requirements similar, in most respects, to those required by the Eyeglass Rule.⁴⁶ When the Commission turned again to the Eyeglass Rule and its prescription release requirement, it held that evidence in the rulemaking record suggested that prescribers continued to refuse to release eyeglass prescriptions, even though such conduct had been unlawful for nearly 25 years.⁴⁷ The Commission opined that were it to eliminate the prescription release requirement, even more prescribers might refuse to release prescriptions and thereby benefit from inducing patients to purchase eyeglasses from them.⁴⁸ Due to this possibility, and because it found the release of prescriptions enhances consumer choice at minimal compliance cost to prescribers, the Commission opted to retain the prescription release requirement.⁴⁹

Furthermore, after reviewing the record and finding that some consumers still were not aware of their right to obtain their prescription, the Commission decided not to modify the Rule to require release upon request. The Commission stated that absent automatic release, consumers unaware of their right would not know to request their prescription, or their prescriber might discourage them from doing so.⁵⁰ In light of these

⁴⁵ 15 U.S.C. 7601-7610 (Pub. L. 108-164).

⁴⁶ Contact Lens Rule, 16 CFR part 315.

⁴⁷ Ophthalmic Practice Rules, Final Rule, 69 FR 5451, 5453 (Feb. 4, 2004).

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.* The Commission also made findings that: release of prescriptions enhances consumer choice; no evidence had been submitted that the Rule’s restrictions on

considerations, the Commission determined to retain the Rule in its existing form.⁵¹ In so doing, the Commission also ensured that prescription release requirements for eyeglasses would align with those for contact lenses under the Contact Lens Rule.⁵²

4. The 2015 to 2020 Contact Lens Rule Review

As part of its periodic review of rules and guides, the Commission, on September 3, 2015, initiated a review of the Contact Lens Rule, including its prescription release requirement.⁵³ While the Contact Lens Rule differs from the Eyeglass Rule in some respects, many of the issues and concerns regarding prescription release and portability are the same, and therefore some of the comments and data submitted during the CLR review are pertinent to the Commission's review of the Eyeglass Rule.

During its review of the CLR, the Commission considered more than 8,000 public comments as it put forth a notice of proposed rulemaking⁵⁴ and supplemental notice of proposed rulemaking⁵⁵ before issuing an amended final rule on August 17, 2020.⁵⁶ In its

disclaimers and waivers were no longer needed; the automatic release provision imposed only a minimal burden on prescribers; and retaining automatic release would keep the Eyeglass Rule consistent with the automatic release provision of the Contact Lens Rule, promulgated in 2004 pursuant to the Fairness to Contact Lens Consumers Act of 2003. *Id.*; see also Contact Lens Rule, 16 CFR part 315; Fairness to Contact Lens Consumers Act, 15 U.S.C. 7601-7610.

⁵¹ Ophthalmic Practice Rules, 69 FR 5451, 5453.

⁵² *Id.* See also Contact Lens Rule, 69 FR 40482 (July 2, 2004) (codified at 16 CFR part 315).

⁵³ Contact Lens Rule, Request for Comment, 80 FR 53272 (Sept. 3, 2015) [hereinafter CLR RFC].

⁵⁴ Contact Lens Rule, Notice of Proposed Rulemaking, 81 FR 88526 (Dec. 7, 2016) [hereinafter CLR NPRM].

⁵⁵ Contact Lens Rule, Supplemental Notice of Proposed Rulemaking, 84 FR 24664 (May 28, 2019) [hereinafter CLR SNPRM].

⁵⁶ Contact Lens Rule, Final Rule, 85 FR 50668 (Aug. 17, 2020) [hereinafter CLR Final Rule].

CLR final rule, the Commission determined that the evidentiary record, as well as the Commission's enforcement and oversight experience, supports the view that prescriber compliance with the automatic prescription release requirement is sub-optimal, and, as a result, that millions of consumers are still not receiving their contact lens prescriptions as required by law.⁵⁷ The Commission further found that many consumers remain unaware that they even have a right to receive their prescriptions.⁵⁸ To remedy this, the Commission implemented a Confirmation of Prescription Release provision, requiring that prescribers request that a patient confirm receipt of their contact lens prescription.⁵⁹ According to the Commission, the patient confirmation requirement should result in, among other things, an increase in the number of patients in possession of their contact lens prescription and improved flexibility and choice for consumers, ultimately fostering improved competition in the market, more efficient contact lens sales, and lower prices for consumers.⁶⁰ The Commission also noted that the requirement would increase the Commission's ability to enforce and assess the CLR.⁶¹

C. The Evolving Eyeglass Marketplace

The retail vision care industry in the United States consists of several different kinds of participants, namely ophthalmologists, optometrists, opticians, and eyewear retailers. The services provided by these different participants often overlap, and the different participants often have business affiliations with each other.

⁵⁷ *Id.* at 50687.

⁵⁸ *Id.*

⁵⁹ 16 CFR 315.3(c).

⁶⁰ CLR Final Rule, 85 FR 50668, 50687.

⁶¹ *Id.*

Ophthalmologists are medical doctors who specialize in treating diseases of the eye. They are the only eye care professionals who can treat all eye and vision system diseases, perform eye surgery, prescribe nearly all manner of drugs, and use any treatment available to licensed physicians. Ophthalmologists can prescribe and sell eyeglasses and contact lenses, and their offices may be attached to an associated optical dispensary. Ophthalmologists have typically completed four years of medical school, a year of general internship, and an additional three years of specialized hospital residency training in ophthalmology. It is estimated that there are approximately 19,000 active ophthalmologists in the United States.⁶² Many ophthalmologists, especially those who further specialize,⁶³ do not sell eyewear, although some do.

Optometrists are doctors of optometry. They have not completed medical school, but have instead completed four years of training in optometry school, following three or more years of college. They are trained and licensed to examine eyes, diagnose refractive problems, prescribe and dispense eyeglasses and contact lenses, and detect eye disease.⁶⁴ As with ophthalmologists, optometrists can prescribe and sell eyeglasses and contact lenses, and their offices are often attached to, or part of, an associated optical dispensary. A government estimate indicates that in 2020 there were approximately 43,000 active

⁶² American Academy of Ophthalmology (“AAO”), “Eye Health Statistics,” <https://www.aao.org/newsroom/eye-health-statistics>.

⁶³ According to the AAO, “[s]ubspecialists have intensive training in a particular area of the eye. To become subspecialists, ophthalmologists add a fellowship to their years of medical training. A fellowship prepares an ophthalmologist to treat more specific or complex conditions in certain parts of the eye or in certain types of patients.” AAO, “Ophthalmology Subspecialists” (June 6, 2016), <https://www.aao.org/eye-health/tips-prevention/ophthalmology-subspecialists>.

⁶⁴ In some states, optometrists can prescribe medicine and perform certain surgeries. AOA, “What’s a doctor of optometry?” <https://www.aoa.org/healthy-eyes/whats-a-doctor-of-optometry?sso=y>.

optometrists in the United States.⁶⁵ While professional services, such as eye health and refraction examinations, generate significant revenue for optometrists, most optometrists still derive a larger percentage of their income from product sales, including the sale of eyeglasses and contact lenses.⁶⁶ According to some estimates, product sales typically account for 55 to 65 percent of optometrist revenue.⁶⁷

Opticians, also known as dispensing opticians or ophthalmic dispensers, act primarily as retail providers of eyeglasses and contact lenses. Opticians fabricate, fit, adjust, and repair eyeglasses, primarily on the basis of prescriptions issued by optometrists and ophthalmologists. Opticians typically are not authorized to examine eyes to determine prescriptions, but may conduct pupillary distance examinations in order to fit a pair of eyeglasses to an individual. Twenty-one states currently require opticians to obtain licenses,⁶⁸ usually through a state-approved course of study and completion of

⁶⁵ Bureau of Labor Statistics, U.S. Dep’t of Labor, Occupational Outlook Handbook, Optometrists, <https://www.bls.gov/ooh/healthcare/optometrists.htm> (visited Apr. 27, 2022).

⁶⁶ ECP University, “Key Metrics: Assessing Optometric Practice Performance & Best Practices of Spectacle Lens Management Report,” 25 (March 22, 2018), https://ecpu.com/media//wysiwyg/docs/ECPU_MBA_KeyMetricsReport_2018.pdf (“Independent optometric practices derive 35% of revenue from professional fees and 65% from product sales, including 37% from [eyeglasses] and 17% from contact lens sales”); Rev. Optm. Bus., “Challenges and Opportunities in the Future of Independent Optometry,” 3 (April/May 2013), https://www.reviewob.com/wp-content/uploads/2016/11/paa_visionsource__0413.pdf (stating that device sales remain the dominant revenue producer in most practices, typically accounting for 55 to 65 percent of revenue).

⁶⁷ *Id.* See also Margery Weinstein, “Key Practice Metrics: Numbers to Track & Grow to Help Speed Practice Recovery,” Rev. Optm. Bus., <https://www.reviewob.com/key-practice-metrics-numbers-to-track-grow-to-speed-practice-recovery/> (citing Care Credit, Independent Optometry Key Performance Metrics: 2019 Trend Report at 5, 9, and noting that product sales in 2019 continued to account for the majority of gross revenue (54%), but that eyeglass sales dropped from 42% of gross revenue in 2018 to 37% in 2019).

⁶⁸ OpticianEDU.org, “Optician Certification,” <https://www.opticianedu.org/optician-certification/>.

an exam. The remaining states have no formal requirements for practice, but many opticians in these states complete some form of apprenticeship or training. A 2020 government estimate indicates that there are approximately 70,000 active opticians in the United States.⁶⁹

Eyewear retailers are companies and independent merchants that sell eyeglasses. They often are owned by, employ, or associate themselves with, ophthalmologists, optometrists, and opticians. Some are considered independent optical retailers (defined as a retailer with three or fewer locations that has either an ophthalmologist, optometrist, optician, or optical retailer on site⁷⁰), while others may be optical chain stores, such as LensCrafters and America's Best, mass merchandisers, such as Costco and Sam's Club, department stores, such as Macy's, or online entities, such as Warby Parker and Zenni Optical.

The overall retail eyeglass market continues to experience growth in both the number of eyeglass wearers as well as the number of eyeglasses purchased. As of December 2019, approximately 165 million American adults were regularly wearing prescription eyeglasses, representing nearly two-thirds of the country's adult populace.⁷¹ In addition, some 30 percent of eyeglass wearers used two or more pairs interchangeably on a regular basis.⁷²

⁶⁹ Bureau of Labor Statistics, U.S. Dep't of Labor, Occupational Outlook Handbook, Opticians, <https://www.bls.gov/ooh/healthcare/opticians-dispensing.htm> (visited Apr. 27, 2022).

⁷⁰ Vision Council, "VisionWatch—The Vision Council Market Analysis Report," Dec. 2019 [hereinafter VisionWatch Report], at 17.

⁷¹ VisionWatch Report, *supra* note 70, at 24; *see generally* Vision Council, "U.S. Optical Overview and Outlook," Dec. 2015, at 4-5 (discussing the growth of eyeglass usage from 2006 to 2015).

⁷² VisionWatch Report, *supra* note 70, at 43.

Overall, in 2019, consumers purchased approximately 79 million pairs of eyeglass frames, and 88 million pairs of lenses⁷³ for a total sales volume of roughly \$10 billion in frames and \$14.3 billion in lenses.⁷⁴ Of total sales, the largest portion—at least in terms of dollars spent—occurred at independent optical retailers, who accounted for approximately 50 percent of U.S. eyeglass frame and lens sales in 2019.⁷⁵ Conventional optical chain stores accounted for approximately 27.5 percent of eyeglass frame and lens sales (in dollars), and mass merchandisers accounted for approximately 10 percent of eyeglass frame and lens sales (in dollars).⁷⁶

Online sales of eyeglasses remain a small portion of the optical market. According to one industry publication, as of June 2019 just five percent of sales (in dollars) of eyeglass frames derived from online sales during the previous year.⁷⁷ Consumers purchased approximately seven and a half million pairs of frames online, representing about 9.4 percent of all pairs of frames sold, in the 12 months ending June

⁷³ In 2019, about 89 percent of prescription lenses were purchased as a complete pair of eyeglasses (frames and lenses), representing about 78.3 million pairs of prescription eyeglasses. VisionWatch Report, *supra* note 70, at 11, 12, 60. By comparison, in 1975, American consumers purchased approximately 53 million pairs of prescription eyeglasses. Eyeglass I Report, *supra* note 6, at 11-12.

⁷⁴ Vision Council, “Consumer Barometer,” Dec. 2019, at 2, 18-19.

⁷⁵ *Id.* at 18-19.

⁷⁶ *Id.* Optical centers in department stores accounted for approximately two percent of frame and lens sales (in dollars). *Id.*

⁷⁷ Vision Council, “U.S. Optical Market Optical Overview,” Sept. 2019, at 12. The industry report does not specify whether the frames were purchased with prescription lenses or by themselves. Other data from the Vision Council, however, indicate that distribution percentages for sales of refractive lenses are nearly identical to that of frames, suggesting that the overall percentage of complete eyeglasses (frames and lenses) purchased online is about 5 percent of total sales (in dollars). Vision Council, “Consumer Barometer,” Dec. 2019, at 18-19. By comparison, approximately 15 percent of sales (in dollars) of contact lenses now derive from online sales. Vision Council, “U.S. Optical Market Optical Overview,” Sept. 2019, at 3, 6.

2019.⁷⁸ But although online sales are still relatively small, they continue to increase steadily. Total online sales (in dollars) for all vision care products rose 7.7 percent between mid-2018 and 2019,⁷⁹ while online sales (in dollars) of frames grew 8.1 percent and of prescription lenses grew 10.8 percent in 2019.⁸⁰ A primary driver for the increase in online sales may be lower pricing. According to an industry source, as of 2015 online sellers were typically 50 to 60 percent less expensive than brick and mortar eyeglass retailers.⁸¹ More recently, the COVID-19 pandemic may have spurred a greater number of consumers to shop for eyeglasses online, or to delay eyewear purchases altogether, but the long-term impact of the pandemic on consumer purchasing decisions is unknown. A study commissioned by The Vision Council showed that, in March 2020, when the World Health Organization declared COVID-19 a pandemic, over 25% of consumers stated an intention to buy eyewear online to limit human interaction and physical contact, more than double the number who planned to shop online before COVID-19.⁸²

D. State Regulation of the Sale of Eyeglasses

As detailed above, the purpose of the Eyeglass Rule is to facilitate consumer choice and foster competition by separating the functions of the eye examination and the dispensing of prescribed eyeglasses. The Rule accomplishes this separation by requiring that prescribers provide consumers with a copy of their eyeglass prescription at the

⁷⁸ Vision Council, “U.S. Optical Market Optical Overview,” Sept. 2019, at 7.

⁷⁹ *See id.* at 6.

⁸⁰ Vision Council, “Consumer Barometer,” Dec. 2019, at 18-19.

⁸¹ Vision Council, “U.S. Optical Overview and Outlook,” *supra* note 71, at 65 n.3.

⁸² Vision Council, “Researching Recovery: Exploring Evolving Consumer Behavior and Industry Response During COVID-19,” May 21, 2020, at 38 (reporting results of VisionWatch Insights study), *available at* https://thevisioncouncil.org/sites/default/files/assets/media/TVC-COVID-19-VisionWatch-Consumer-Industry-Research_Member-Insights-Webinar-5-21-2020_w-Notes.pdf.

conclusion of the eye examination, and by prohibiting certain restrictions on the release of the prescription. The Eyeglass Rule, however, regulates only the release of the eyeglass prescription, and does not regulate other aspects of the practice of ophthalmology, optometry, or opticianry.⁸³

State laws and regulations govern most aspects of professional practice and eyewear sales. Typically, individual state licensing boards are responsible for the licensing and oversight of ophthalmologists, optometrists, and opticians and, often, the dispensing of prescribed eyeglasses. These state regulatory frameworks vary widely. Some states have comprehensive regulatory frameworks that govern every aspect of dispensing prescribed eyeglasses: such regulations set forth the required components of an eyeglass prescription, the length and expiration date of an eyeglass prescription, and the allowable modes to transmit eyeglass prescriptions, as well as recordkeeping requirements.⁸⁴ Other states regulate less comprehensively. For example, some states require opticians to dispense eyeglasses only upon the written prescription of a prescriber,⁸⁵ while other states allow more flexibility.⁸⁶ Further, some states that require a prescription for the sale of eyeglasses do not explicitly set forth specific components of an eyeglass prescription.⁸⁷ State regulatory frameworks also differ on expiration dates for

⁸³ For example, although the Eyeglass Rule contains a definition of “prescription,” the purpose of the definition is to effectuate the separation of the exam and the sale of eyeglasses. The Rule’s definition is not intended to preempt state regulations. *See* 16 CFR 456.1(g).

⁸⁴ *See* Alaska Stat. Ann. §§ 48.310, 48.920; La. Admin. Code tit. 46, § LI-505.

⁸⁵ *See* Ky. Rev. Stat. Ann. § 320.300; N.Y. Comp. Codes R. & Regs. tit. 18, § 505.6.

⁸⁶ Mass. Gen. Laws Ann. ch. 112, § 73C (permitting duplications, replacements, reproductions or repetitions at retail without a prescription); N.C. Gen. Stat. Ann. § 90-235 (same).

⁸⁷ N.C. Gen. Stat. Ann. § 90-236.1; Del. Code Ann. tit. 24, § 2122.

eyeglass prescriptions: some states require that eyeglass prescriptions expire within a certain period;⁸⁸ some states mandate that prescriptions be valid for at least a certain amount of time;⁸⁹ other states leave that determination to the prescriber;⁹⁰ while still other states are silent on the issue.⁹¹

II. Eyeglass Rule Review

A. Evidentiary Standard

The Commission promulgated the Eyeglass Rule under section 18 of the FTC Act, which grants the Commission the authority to adopt rules defining unfair or deceptive acts or practices in or affecting commerce.⁹² When amending or repealing the Rule, the Commission must follow the same section 18 procedures governing the adoption of rules,⁹³ and in doing so, engages in a multi-step inquiry. To make a determination that a practice is unfair, the Commission evaluates the following questions:

⁸⁸ D.C. Mun. Regs. tit. 17, § 6416.1 (expiration of 1 year after the issue date unless there is a medical reason that warrants a prescription for less than 1 year.); Fla. Stat. Ann. § 463.012 (eyeglass prescriptions shall be considered valid for a period of 5 years).

⁸⁹ Cal. Bus. & Prof. Code § 2541.1 (“The expiration date of a spectacle lens prescription shall not be less than two to four years from the date of issuance unless medical reason for earlier reexamination”); Mich. Comp. Laws Ann. § 333.5557 (setting expiration date of no less than 1 year from the date of the examination unless medical reason for shorter time).

⁹⁰ 852 Ind. Admin. Code 1-5.1-1 (stating it is the optometrist’s responsibility to determine the expiration of the prescription.); Kan. Admin. Regs. § 65-8-4 (requiring prescriber to include on the prescription the “expiration date, if appropriate”).

⁹¹ Ark. Code Ann. § 17-90-108 (A)(3) (providing expiration term for contact lens prescriptions, but not for eyeglass prescriptions); Wis. Admin. Code Opt § 5.02 (providing that a contact lens prescription must contain the date of expiration, but making no mention of the expiration of eyeglass prescriptions).

⁹² 15 U.S.C. 57a(a)(1)(B).

⁹³ 15 U.S.C. 57a(d)(2)(B) which states a substantive amendment to, or repeal of, a rule promulgated under subsection (a)(1)(B) shall be prescribed, and subject to judicial review, in the same manner as a rule prescribed under that subsection.

- (1) Does the act or practice cause or is it likely to cause substantial injury to consumers?
- (2) Is the injury to consumers outweighed by countervailing benefits that flow from the act or practice at issue? and (3) Can consumers reasonably avoid the injury?⁹⁴

If an act or practice is deemed unfair, the Commission may issue a notice of proposed rulemaking under section 18 only where it has “reason to believe” that the unfair act or practice at issue is “prevalent.”⁹⁵ The Commission can find prevalence where information available to it indicates a widespread pattern of unfair or deceptive acts or practices.⁹⁶ Once the Commission finds that an unfair act or practice is prevalent, it has wide latitude in fashioning a remedy and need only show a “reasonable relationship” between the unfair act or practice and the remedy.⁹⁷

In making this proposal, the Commission has relied on a record that includes public comments received in response to the Commission’s 2015 advance notice of proposed rulemaking (“ANPR”) that initiated this rule review,⁹⁸ and incorporates the rulemaking record for the 2020 amendments to the CLR to the extent that record provides information pertinent to the prescription release provision of the Eyeglass Rule.⁹⁹ The

⁹⁴ 15 U.S.C. 45(n); *see also* Eyeglass II Rule, 54 FR 10285, 10287; Letter from the FTC to Hon. Wendell Ford and Hon. John Danforth, Committee on Commerce, Science and Transportation, United States Senate, Commission Statement of Policy on the Scope of Consumer Unfairness Jurisdiction (December 17, 1980), *Appended to International Harvester Co.*, 104 F.T.C. 949, 1070, 1073 (1984).

⁹⁵ 15 U.S.C. 57a(b)(3).

⁹⁶ 15 U.S.C. 57a(b)(3)(B).

⁹⁷ *Am. Fin. Servs. Ass’n v. FTC*, 767 F.2d 957, 988 (D.C. Cir. 1985) (quoting *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612-13 (1946)).

⁹⁸ Ophthalmic Practice Rules (Eyeglass Rule), Advance Notice of Proposed Rulemaking; Request for Comment, 80 FR 53274 (Sept. 3, 2015) [hereinafter Eyeglass Rule ANPR].

⁹⁹ The 2020 Contact Lens Rulemaking record includes comments to the CLR RFC; the CLR NPRM; the Public Workshop Examining Contact Lens Marketplace and Analyzing Proposed Changes to the Contact Lens Rule; Public Workshop and Request for Public

Commission has also examined the state of the marketplace and the content of consumer complaints about prescriber practices. Further, the Commission remains cognizant of the lengthy history and record that supported the enactment of the Eyeglass Rule and the CLR. Based on the entire record for the Rule, the Commission has reason to believe that prescribers' failure to automatically provide consumers with prescriptions at the completion of an eye exam—held to be an unfair act or practice when the Eyeglass Rule was enacted—remains prevalent, and millions of Americans every year are not receiving their eyeglass prescriptions as required by law. The Commission also believes that a risk of significant harm to consumers continues to exist and that, without the Rule's requirements, consumers could not reasonably avoid the injury resulting from the unfair acts and practices prohibited by the Rule. Further, the Commission believes that documentation of prescription release is necessary to better effectuate compliance with, as well as enforcement of, the Rule. Consequently, the Commission proposes amending the Rule to implement a Confirmation of Prescription Release requirement similar to that now required by the CLR.¹⁰⁰ Pursuant to these amendments, prescribers would be required to do one of the following:

- (i) Request that the patient acknowledge receipt of the prescription by signing a separate statement confirming receipt of the prescription;

Comment, 82 FR 57889 (Dec. 8, 2017) [hereinafter CLR WS]; and the CLR SNPRM. Public comments received in response to these notices are available on Regulations.gov. <https://www.regulations.gov/document/FTC-2015-0093-0001> (CLR RFC Comments); <https://www.regulations.gov/document/FTC-2016-0098-0001> (CLR NPRM Comments); <https://www.regulations.gov/document/FTC-2017-0099-0001> (CLR WS Comments); and <https://www.regulations.gov/document/FTC-2019-0041-0001> (CLR SNPRM Comments). Regulations.gov has assigned each comment an identification number appearing after the name of the commenter. This notice cites comments using the last name of the individual submitter, or the name of the organization and the individual within the organization who submitted the comment, along with the comment identification number assigned by Regulations.gov.

¹⁰⁰ 16 CFR 315.3.

(ii) Request that the patient sign a prescriber-retained copy of a prescription that contains a statement confirming receipt of the prescription;

(iii) Request that the patient sign a prescriber-retained copy of the sales receipt for the examination that contains a statement confirming receipt of the prescription; or

(iv) If a digital copy of the prescription was provided to the patient (via methods including an online portal, electronic mail, or text message), retain evidence that such prescription was sent, received, or made accessible, downloadable, and printable. The Commission's proposal provides sample language for confirmation options (i), (ii), and (iii), but also allows prescribers to craft their own wording of the signed confirmation for these options if they so desire. As with the CLR's Confirmation requirement, the proposed Confirmation of Prescription Release requirement for eyeglass prescriptions would apply only to prescribers with a direct or indirect financial interest in the sale of eyeglasses.

The Commission believes that the proposed amendment will prevent consumer harm, and that the proposed amendment is necessary to remedy demonstrated failures of some providers to automatically release prescriptions at the completion of an eye examination, and to ensure a competitive marketplace for eyeglasses. The Commission notes that providers who comply with the automatic release provision of the Rule may face a competitive disadvantage because of the widespread non-compliance of other providers. This creates an unlevel playing field and undermines competition. The Commission is sensitive to any additional burden or cost that this rule change imposes on business. However, it believes that this proposal maximizes the benefits of comparison-shopping with a relatively small burden or cost on business. The potential benefit of increasing the number of patients in possession of their eyeglass prescriptions is substantial: namely, increased flexibility and choice for consumers; a reduced likelihood of errors associated with incorrect, invalid, and expired prescriptions, and consequently,

improved patient safety; and an improved ability for the Commission to enforce and monitor prescriber compliance with the Rule's prescription release requirements.

The proposal would also align the prescription release related provisions of the Rule with the CLR, thereby reducing confusion and complexity that might arise for consumers and prescribers from having different prescription release requirements for eyeglass and contact lens prescriptions. In addition, because the CLR already obligates ophthalmologists and optometrists to release contact lens prescriptions, to obtain a confirmation, and to maintain records, the marginal cost of the proposed amendment to the Eyeglass Rule would be extremely low. Prescribers likely have forms and systems in place already, which may need only minor adjustments to accommodate confirmations for eyeglasses prescriptions.

The Commission also proposes permitting prescribers to comply with automatic prescription release via electronic delivery in certain circumstances.¹⁰¹ The Commission does not propose, at this time, to implement other recommendations about which it requested comment in the ANPR, including requiring prescribers to provide duplicate copies of prescriptions to patients; to provide a copy of a prescription to, or verify a prescription with, third-party sellers; or to add pupillary distance to prescriptions.

B. Overview of Comments in Response to ANPR

In September 2015, as part of its routine review of Commission rules and guides, the Commission published the ANPR seeking public comment on, among other things: the continuing need for the Rule; the Rule's economic impact and benefits; possible conflict between the Rule and state, local, or other federal laws or regulations; and the

¹⁰¹ See Section IV.B.2.a, *infra*. The Commission also clarifies that the presentation of proof of insurance coverage shall be deemed to be a payment for the purpose of determining when a prescription must be provided under 16 CFR 456.2(a), a clarifying, technical rule amendment. See Section IV.B.3, *infra*. The Commission further clarifies that the term "eye examination" used in the Rule refers to a refractive eye examination. See Section V.C, *infra*.

effect on the Rule of any technological, economic, or other industry changes. The Commission also sought comment on the following specific questions: should the definition of “prescription” be modified to include pupillary distance; should the Rule be extended to require that prescribers provide their patients with a duplicate copy of a prescription; and should the Rule be extended to require that a prescriber provide a copy to or verify a prescription with third parties authorized by the patient?¹⁰²

This notice of proposed rulemaking summarizes the comments received in response to the ANPR and explains why the Commission continues to believe that the Eyeglass Rule is necessary. It also explains why the Commission is proposing certain amendments and why it declines to propose others. Additionally, it seeks additional comment on certain questions. Finally, the NPRM sets forth the Commission’s regulatory analyses under the Regulatory Flexibility and Paperwork Reduction Acts, as well as the text of the proposed amendments.

The Commission received 868 comments in response to the ANPR from a variety of individuals and entities, including ophthalmologists, optometrists, opticians, trade associations, consumers (and representatives of consumers), and eyeglass sellers.¹⁰³ Virtually all of the comments supported retaining the Rule. Some commenters, including trade associations that represent opticians and retailers that employ optometrists and opticians, stated that the Rule is needed because some prescribers still are not

¹⁰² Eyeglass Rule ANPR, 80 FR 53274, 53276.

¹⁰³ The comments are posted at <https://www.regulations.gov/document/FTC-2015-0095-0001>. This document cites comments from the Eyeglass Rule ANPR using the comment number assigned by Regulations.gov without the preceding identification “FTC-2015-0095.” The citations also include: for comments submitted by individuals, the last name of the commenter; and for comments submitted on behalf of organizations, the name of the organization and the last name of the individual submitting on behalf of the organization. For instance, the full comment number assigned by Regulations.gov to the comment submitted by an individual named Publi is FTC-2015-0095-0040. In this document, that comment is cited as “Publi (Comment #0040)”.

automatically releasing prescriptions and some consumers face resistance when they try to obtain their prescriptions.¹⁰⁴ The AOA, which represents approximately 33,000 doctors of optometry, questioned the continued need for the Rule based on its understanding that doctors of optometry widely comply with the Rule’s requirements, but stated that the Rule—as currently drafted—is not necessarily harmful.¹⁰⁵

Warby Parker, a large online eyeglasses retailer,¹⁰⁶ and a few consumers indicated their belief that ordering eyeglasses online is a good option as it provides consumers with an affordable and convenient choice.¹⁰⁷ Some indicated their support for Rule changes that would permit online sales to occur with greater ease. Specifically, some commenters supported requirements for prescribers to provide copies of prescriptions to authorized third-party sellers upon a seller’s request and to provide duplicate copies of prescriptions

¹⁰⁴ See, e.g., Opticians Association of Virginia (Comment #0647 submitted by Nelms) (stating that patients are led into the dispensary before paying for their exam and requesting the Rule be amended to include language that the prescription be given to the patient without additional sales pressure or intimidation); Burchell (Comment #0866); NAOO (Comment #0748 submitted by Cutler); Professional Opticians of Florida (Comment #0803 submitted by Couch). Other commenters more generally stated their support for the Rule. See Publi (Comment #0040); Santini (Comment #0047); Costa (Comment #0068); Ellis (Comment #0189); Hildebrand (Comment #0220); Prevent Blindness (Comment #0385 submitted by Parry); DiBlasio (Comment #0441); Pulido (Comment #0019); Stuart (Comment #0841).

¹⁰⁵ Comment #0849 submitted by Peele; *see also* Barnes (Comment #0043) (stating she complies with the Rule although it is unnecessary since any ethical doctor will release a non-expired prescription to a patient); Kanevsky (Comment #0364) (optometrist states she and the prescribers she knows comply with the Rule).

¹⁰⁶ Warby Parker, which began as an online-only entity but now has over 100 brick and mortar locations in the U.S., began operations in 2010 and appears to be the largest online eyeglass seller. VisionMonday, “Top 50 U.S. Optical Retailers 2020,” *available at* <https://www.visionmonday.com/vm-reports/article/key-optical-players-ranked-by-us-sales-in-2019/>.

¹⁰⁷ Thompson (Comment #0333); Berge (Comment #0352); Warby Parker (Comment #0817 submitted by Kumar); *see also* Senate Majority Leader Charles Schumer (Comment #0865).

to patients upon request.¹⁰⁸ Some commenters also suggested the Rule should require prescribers to post a “bill of rights” or conspicuous signage of consumers’ rights to a copy of their prescription.¹⁰⁹ Some commenters also expressed support for adding a requirement that prescriptions include pupillary distance—a measurement needed for consumers to order eyeglasses online—and for the Rule to prohibit eyeglass prescriptions from including any expiration dates, or at least unnecessarily short-term expiration dates.¹¹⁰

On the other hand, many prescribers felt the Commission should limit, ban, or regulate the online sale of eyeglasses on grounds that such sales are less safe because eyeglasses sold online do not always adhere to prescription specifications and glass impact-resistance requirements.¹¹¹ Some prescribers commented that their offices are burdened by the problematic practices of internet-based eyewear companies, since the

¹⁰⁸ See, e.g., DeMuth, Jr. (Comment #0055); Jozwik (Comment #0002); Schwartz (Comment #0514); Opticians Association of Virginia (Comment #0647 submitted by Nelms); Pulido (Comment #0019); Warby Parker (Comment #0817 submitted by Kumar); see also NAOO (Comment #0748 submitted by Cutler); Professional Opticians of Florida (Comment #0803 submitted by Couch); Opternative (now Visibly) (Comment #0853 submitted by Dallek).

¹⁰⁹ Tedesco (Comment #0042) (signage); Warby Parker (Comment #0817 submitted by Kumar) (bill of rights and signage).

¹¹⁰ See, e.g., Hildenbrand (Comment #0049) (expiration); Fainzilberg (Comment #0051) (pupillary distance); Wintermute (Comment #0067) (pupillary distance); Cordivari (Comment #0069) (expiration); Dickens (Comment #0176) (pupillary distance); O’Dea (Comment #0188) (pupillary distance); Nystrom (Comment #0254) (expiration); Meszaros (Comment #0303) (expiration); Buntain (Comment #0529) (expiration); Morel (Comment #0712) (expiration); Warby Parker (Comment #0817 submitted by Kumar) (expiration and pupillary distance).

¹¹¹ See, e.g., Pentecost (Comment #0626); Bolenbaker (Comment #0633); McWilliams (Comment #0635); Cervantes (Comment #0671); Harrison (Comment #0718); Nellis (Comment #0725); Ambler (Comment #0025).

patient ultimately goes to their prescriber for a remedy if they have an issue with their online eyeglass purchase.¹¹²

The AOA stated that the Rule should not require prescribers to provide additional copies of prescriptions to consumers because prescribers must be allowed to use their clinical judgment to determine whether it is appropriate to provide additional copies after the eye exam was performed.¹¹³ The organization also questioned the FTC's authority to add a requirement to the Rule mandating that prescribers respond to authorized third-party requests.¹¹⁴ The American Academy of Ophthalmology ("AAO"), the largest national member association of ophthalmologists, stated that it was unaware of any significant issues with consumers receiving duplicate copies of their prescriptions from ophthalmologists, noting that its members put significant time and resources into ensuring patients receive prescriptions in a timely manner and traditionally provide duplicates without charge.¹¹⁵

Further, the AOA, the AAO, and individual prescribers commented that the Rule should not require that a prescription include pupillary distance, because, among other reasons, they believe this measurement is part of the dispensing of eyeglasses, and not part of a refractive examination.¹¹⁶ Prescribers also generally did not support having an

¹¹² AOA (Comment #0849 submitted by Peele); Pentecost (Comment #0626); McWilliams (Comment #0635); Nellis (Comment #0725); Diener (Comment #0017). The AOA also stated its concern that some online retailers may be using foreign manufacturers with questionable labor standards. Comment #0849.

¹¹³ Comment #0849 submitted by Peele. The AOA also stated that it is already common practice for prescribers to provide duplicate copies of prescriptions upon request. *Id.*

¹¹⁴ *Id.*

¹¹⁵ Comment #0864 submitted by Haber.

¹¹⁶ *See, e.g.*, AAO (Comment #0864 submitted by Haber); AOA (Comment #0849 submitted by Peele); Johnson (Comment #0654); Nichols (Comment #0461); Patterson (Comment #0469); Chung (Comment #0474); Wareham (Comment #0498); Yuhas

expiration date of more than one year for eyeglasses, or requested that the FTC defer to state law and the medical judgment of prescribers to determine if and when a prescription should expire.¹¹⁷

A number of optician groups commented that the Rule should require that eyeglass dispensers only sell eyeglasses after obtaining a copy of a prescription, or verifying a prescription with the prescriber, to ensure the safety of their patients.¹¹⁸ They also largely did not want the Rule to require that prescriptions include pupillary distance because they prefer to take this measurement and not be required to follow a measurement taken by the prescriber.¹¹⁹ In addition, although many opticians stated a preference for a one-year expiration date, they did not object to a two-year expiration period unless a medical reason exists for requiring a shorter period of time.¹²⁰

III. Requirements for Eyeglass Sellers

Although the Eyeglass Rule imposes certain requirements and limitations on prescribers—namely that they automatically release eyeglass prescriptions and do not charge fees or demand liability waivers for doing so—the Rule does not otherwise regulate the sale of eyeglasses. In this respect, the Eyeglass Rule diverges from the

(Comment #0505); Mangano (Comment #0525); Hopkins (Comment #0776); Alvarez (Comment #0838).

¹¹⁷ See, e.g., AAO (Comment #0864 submitted by Haber); AOA (Comment #0849 submitted by Peele).

¹¹⁸ See, e.g., Opticians Association of America (Comment #0638 submitted by Allen); Opticians Association of Kentucky (Comment #0640 submitted by Castle); Opticians Association of Vermont (Comment #0641 submitted by Williams); Opticians Alliance of New York (Comment #0642 submitted by Cullen); Opticians Association of Ohio (Comment #0683 submitted by Gasper); Opticians Association of Iowa (Comment #0646 submitted by Dalton); South Carolina Association of Opticians (Comment #0822 submitted by Harbert).

¹¹⁹ *Id.*

¹²⁰ *Id.*

Contact Lens Rule. For example, among other things, the CLR provides that a dispenser may only sell contact lenses in accordance with a valid prescription that is either presented to the seller or verified by the prescriber.¹²¹ The CLR is based on the language Congress set forth in the FCLCA, 15 U.S.C. 7603, whereas the Eyeglass Rule is more narrowly tailored and does not regulate the terms of sale for eyeglasses. The Commission's September 3, 2015 ANPR did not specifically request comment on this issue. However, in response to the Commission's request for feedback on general issues, including its request for modifications to the Rule that may increase benefits to consumers, some commenters offered their views on this topic, with many opining that the FTC should more closely regulate eyeglass sales.

In particular, the Opticians Association of America, a national organization of opticians with over 10,000 members, commented that to ensure patient safety, the Commission should mandate that all sellers only sell eyeglasses after obtaining a copy of the prescription, or after verifying the prescription information with a prescriber.¹²²

¹²¹ See 16 CFR 315.5(a).

¹²² Comment #0638 submitted by Allen; *see also* Opticians Association of Kentucky (Comment #0640 submitted by Castle); Opticians Association of Vermont (Comment #0641 submitted by Williams); Opticians Alliance of New York (Comment #0642 submitted by Cullen); Duff (Comment #0653); Opticians Association of Ohio (Comment #0683 submitted by Glasper); Parent (Comment #0693); Groenke (Comment #0697); Kline (Comment #0710); Schrup (Comment #0765); Kuhl (Comment #0766); Gorsuch (Comment #0773); Frein (Comment #0774); Hopkins (Comment #0776); Feldman (Comment #0780); Anderson (Comment #0781); Lyden (Comment #0792); Jackson (Comment #0707); Meinke (Comment #0795); Lorenczi (Comment #0796); Keas (Comment #0798); Burkhart (Comment #0805); Albee (Comment #0806); Rivera (Comment #0809); Warden (Comment #0820); Anderson (Comment #0714); South Carolina Association of Opticians (Comment #0822 submitted by Harbert); Sansbury (Comment #0825); Williamson (Comment #0827); Ardis (Comment #0830); Folline Vision Centers (Comment #0837); Rump (Comment #0843); Murtha (Comment #0844); Heaton (Comment #0845); Gage-Halman (Comment #0846); Malonjao (Comment #0856); Jozwik (Comment #0002) (commenting that verification minimizes mistakes since the information is straight from the prescriber).

Some commenters also stated that eyeglasses sold online are inferior in quality, or may come with an incorrect prescription.¹²³ The Opticians Association of Alaska, Inc., for example, commented that much of the eyewear sold online “does not meet national tolerance standards,” and asserted that consumers often rely on brick and mortar dispensaries to remedy problems stemming from poorly manufactured eyeglass products purchased online.¹²⁴

The Opticians Association of America and others commented that consumers’ eye health may be negatively affected by unrestricted sales practices, and called the lack of required verification for sellers a “loophole” in the Rule.¹²⁵ Other commenters proposed that, regardless of whether a prescription is presented or verified, the online sale of eyeglasses should be limited or even banned altogether.¹²⁶

However, commenters submitted very little empirical evidence of consumer harm that would support restrictions on sales practices. The only data referenced or submitted in support of additional Commission regulation of eyeglass sales was a 2010 study focusing solely on the online sale of eyeglasses. That study, conducted by Dr. Karl Citek¹²⁷ and others, found that many eyeglasses sold by online retailers did not pass

¹²³ *See, e.g.*, Strahl (Comment #372); Senate Majority Leader Charles Schumer (Comment #0865); Pentecost (Comment #0626); Harrison (Comment #0718); Nellis (Comment #0725).

¹²⁴ Comment #0852 submitted by Brand.

¹²⁵ Opticians Association of America (Comment #0638 submitted by Allen); Opticians Association of Kentucky (Comment #0640 submitted by Castle); Opticians Association of Vermont (Comment #0641 submitted by Williams); Opticians Alliance of New York (Comment #0642 submitted by Cullen); Opticians Association of Ohio (Comment #0683 submitted by Glasper); South Carolina Association of Opticians (Comment #0822 submitted by Harbert).

¹²⁶ *See, e.g.*, Opticians Association of Alaska, Inc. (Comment #0852 submitted by Brand); Kline (Comment #0710).

¹²⁷ Dr. Citek is an optometrist and university professor. *See* <https://www.pacificu.edu/about/directory/people/karl-citek-ms-od-phd-faao>.

ANSI (American National Standards Institute) standards for prescription accuracy or safety.¹²⁸ In the study, ten individuals (consisting of the researchers and their colleagues and associates) ordered two pairs of eyeglasses apiece from ten online sellers.¹²⁹ The published report does not identify the sellers used, stating only that they were online eyeglass sellers with the ten highest page rankings (most visited) at the time.¹³⁰ According to the report, the eyeglasses purchased, and subsequently received in the mail, were then tested by an individual—described in the study as a researcher¹³¹—for prescription accuracy, and tested by an independent laboratory for impact-resistance.¹³² The study found that of the eyeglasses purchased online, 28.6 percent contained at least one lens that failed at least one parameter of optical analysis,¹³³ and 22.1 percent had at least one lens that failed impact testing at the lab.¹³⁴

The Commission has reviewed the Citek study and has significant reservations about the study’s conclusion that eyeglasses purchased online might not be “of equal

¹²⁸ Karl Citek *et al.*, “Safety and compliance of prescription spectacles ordered by the public via the Internet,” *Optometry*, 82 (2011) 549-55.

¹²⁹ *Id.* at 550.

¹³⁰ *Id.*

¹³¹ *Id.* The study does not identify the researcher except by the initials “DLT,” which correspond to one of the article’s authors, Daniel L. Torgersen. At the time, Torgersen was Vice President of Management Information Systems and Special Projects for the Walman Optical Company, an ophthalmic products provider, and technical director of the Optical Laboratories Association. *Id.* at 549; *see also*, VisionMonday, *OLA Announces 2009 Directors’ Choice Recipient and Awards of Excellence Final Nominees* (Oct. 2009), *available at* <https://www.visionmonday.com/latest-news/article/ola-announces-2009-directors-choice-recipient-and-awards-of-excellence-final-nominees-16057/?msclkid=740f9983c64b11ec8e35481006e0819a>.

¹³² Citek, *supra* note 128, at 550. The independent laboratory is not identified.

¹³³ The parameters analyzed included sphere power, cylinder power, cylinder axis, and horizontal prism imbalance. *Id.* at 552.

¹³⁴ *Id.* at 554.

performance, value, or safety” as those dispensed in person.¹³⁵ Significant weaknesses in the study’s design and reporting limit its usefulness. For example, the study does not name the individual online retailers from whom lenses were purchased, nor provide results for each retailer in the study. Hence, even for the ten retailers in question, it is not possible to determine whether the 28.6 percent and 22.1 percent average failure rates reported are typical failure rates or are skewed due to significantly higher failures among a small number of relatively poorly performing actors. In addition, the study does not report how click-rates correspond to sales in the online market. Hence, it is unclear whether those online retailers were also the ten leading online retailers in terms of sales (either in dollars or pairs of eyeglasses), whether they accounted for any particular percentage of online eyeglass sales overall, or whether they were, by some measure, representative of online sellers generally.

It is also unclear whether the Citek study’s reported failure rate for online sellers is any different from that for eyeglasses purchased from traditional optical dispensaries. The study did not include eyeglasses purchased directly from prescribers or brick and mortar dispensaries.¹³⁶ The study does note, however, that, according to a previous study

¹³⁵ *Id.* at 555.

¹³⁶ While none of the commenters submitted or referenced any additional studies evaluating eyeglass sales practices, the Commission is aware of a 2016 study from the United Kingdom analyzing the acceptability, quality, and accuracy of glasses purchased online and from optometry practices. Alison J. Alderson *et al.*, “A Comparison of Spectacles Purchased Online and in UK Optometry Practice,” *Optometry and Vision Science*, 93 (2016) 1196-1202. The study involved 33 eyeglass wearers who purchased 154 pairs of eyeglasses online and 155 pairs in person from optometry practices in the United Kingdom. Eyeglasses were evaluated based on participant-reported preference, acceptability, and safety; an assessment of lens, frame and fit quality; and the accuracy of prescriptions to an international standard. Compared to the practice eyeglasses, participants rated more of the online eyeglasses unacceptable or unsafe due to poor fit, poor cosmetic appearance, or inaccurate optical centration distance. While participants preferred eyeglasses purchased from optometry practices to those purchased online, lens quality and prescription accuracy were similar between the two groups. Frame quality differed based on price, and the authors noted that the online frames were significantly

published in 1978, approximately 25 percent of eyewear manufactured for traditional dispensaries fail at least one parameter of optical analysis, a rate comparable to the online failure rate cited in the Citek study.¹³⁷

In addition, the Citek study is a decade old, and was conducted when the online sale of eyeglasses was in its relative infancy. The eyeglass market has changed considerably since 2010, and it is probable that online sales have changed in various ways: new sellers have entered the market, seller market shares have probably shifted (as well as relative page visits and click-through rates), and online vendors from 2010 who are still operating may have modified their business practices. Because of these and other concerns about the study, the Commission cannot accord it significant weight.

less expensive and thus lower quality. The study authors noted areas for potential improvement in sales practices both for online sellers and optometry practices.

This study is informative of the types of problems eyeglass wearers can encounter in an online or in person purchase and the preferences that may motivate consumers when choosing where to purchase eyeglasses, but the Commission does not believe it provides an adequate basis for imposing further regulatory requirements on eyeglass sellers. The study took place in the United Kingdom, rather than the United States, and online retailers were limited to those with a base in the United Kingdom, so the results are not necessarily applicable to the US market. The study had design limitations similar to the Citek study, such as not identifying the online retailers (or, in this case, the optometry practices), or providing the results for each retailer. Study authors selected online retailers based on search engine results, rather than sales volume, while study participants selected their own optometry practices within a limited set of restrictions. In addition, 97% of study participants had previously purchased their eyeglasses from optometry practices (and may have chosen to purchase from those same practices as part of the study), which might have led to confirmation bias in the self-reported assessments. Moreover, the study findings did not support a meaningful difference in the quality or accuracy of glasses purchased online as compared to those purchased in person.

¹³⁷ See Citek, *supra* note 128, at 554 (citing G.A. Chase & B.E. Lynch, “An Examination of Ophthalmic Prescription Spectacle Quality Relative to the American National Standard Z80.1-1972,” *Optical Index* 1978; 53: 17-52). According to Citek, a subsequent unpublished study found that most of these failures are caught during secondary inspections before the eyeglasses leave the lab for the dispensary. *Id.* at 554. Because the testing in each of the three studies discussed herein was performed by different researchers in different settings in different decades, it is impossible to know if they were performing the same exact tests in the same exact manner, so comparisons between the Citek study and the other two studies are likely of questionable value.

Even if the Citek study were more compelling, however, it is unlikely it would provide, by itself, sufficient justification for adding new regulatory requirements to the Rule. The evidentiary record as a whole does not contain sufficient empirical evidence establishing that current eyeglass sales practices, whether by online vendors or competing brick and mortar establishments, are harmful to consumers and, therefore, should be banned or otherwise restricted. If the Commission had evidence of significant harm associated with one distribution channel in particular, it would need to assess whether new regulatory restrictions would ameliorate those harms in a way that would provide a net benefit to consumers. Furthermore, the Commission notes that certain states expressly permit sellers to duplicate eyeglasses, or do not require written prescriptions to make eyeglasses,¹³⁸ and a Commission regulation requiring presentation of a prescription or verification of a prescription would have to preempt these state laws. The Commission declines to take such action without more compelling empirical evidence of consumer harm or benefits.

IV. Section 456.2—Separation of Examination and Dispensing

A. Automatic Prescription Release

Section 456.2(a) of the Eyeglass Rule provides that it is an unfair act or practice for a prescriber to fail to provide to the patient one copy of the patient's prescription immediately after the eye examination is completed. This provision provides, however, that a prescriber may refuse to give the patient a copy of the patient's prescription until the patient has paid for the eye examination, but only if that prescriber would have required immediate payment from that patient had the eye examination revealed that no

¹³⁸ See, e.g., Mass. Gen. Laws ch. 112, § 73C (duplication, replacements, reproductions, or repetitions may be done at retail without prescription); S.C. Code Ann. § 40-38-280 (duplications, replacements, reproductions, or repetitions may be provided without prescription).

ophthalmic goods were required.¹³⁹ Sections 456.2(b) and 456.2(c) prohibit prescribers from imposing conditions for patients to receive eye examinations and prescriptions. Section 456.2(b) provides that it is an unfair act or practice for a prescriber to condition the availability of an eye examination on a requirement that the patient agree to purchase any ophthalmic goods from the prescriber. Section 456.2(c) provides that it is an unfair act or practice for a prescriber to charge any fee in addition to the examination fee as a condition for releasing the prescription to the patient.

These provisions, typically referred to as the automatic prescription release requirement (also sometimes referred to historically as the required “separation of examination and dispensing”),¹⁴⁰ were intended to ensure that consumers have “unconditional access” to their ophthalmic prescriptions so they are able to “price shop” for eyeglasses.¹⁴¹ As noted in the Eyeglass I Report, without the ability to unconditionally obtain their prescriptions, consumers lack available information to choose the mixture of quality and price that best satisfies their needs.¹⁴²

5. Comments on Whether to Retain Automatic Prescription Release

In response to a request for comments on the continuing need for the automatic prescription release provision,¹⁴³ many commenters—including opticians, optometrists, ophthalmologists, eyeglass sellers, and consumers—expressed strong support. Several

¹³⁹ 16 CFR 456.2(a).

¹⁴⁰ 16 CFR 456.2; *see also* Presiding Officer’s Report, *supra* note 33, at 17-24, 206.

¹⁴¹ Eyeglass I Rule, 43 FR 23992, 23992.

¹⁴² Eyeglass I Report, *supra* note 6, at 265 (citing hearing testimony from the then-Commissioner of the New York City Department of Consumer Affairs).

¹⁴³ Eyeglass Rule ANPR, 80 FR 53274, 53275.

stated that the provision benefits consumers by fostering comparison-shopping and competition.¹⁴⁴ As one consumer commented, “[o]btaining a prescription for my eyeglasses has been crucial, improving my ability to purchase glasses at fair prices.”¹⁴⁵ Another declared that the Rule “has provided consumers the benefit of choosing where they’d prefer to buy their eyeglasses, saving them money on that expense.”¹⁴⁶

Other commenters stressed a continuing need for this provision in the Rule, with some contending that the need is as great or greater now as when the Rule was first implemented. According to one comment (submitted on behalf of three individuals), the advent of online optical dispensaries can put more pressure on prescriber profits, making it even more vital to mandate automatic release in order to ensure that prescribers do not try to recoup lost profits by coercing patients to buy eyewear in-house.¹⁴⁷ According to this comment, the automatic release provision compels prescribers to remain competitive, leading to lower prices and higher quality eyeglasses.¹⁴⁸ Another commenter, the Professional Opticians of Florida, stated that since the Rule was first implemented, there has been a “dramatic increase” in prescribers’ offices with attached optical dispensaries,

¹⁴⁴ See, e.g., Publi (Comment #0040); Ellis (Comment #0189); Prevent Blindness (Comment #0385 submitted by Parry); DiBlasio (Comment #0441); Kelley (Comment #0804); Opternative (now Visibly) (Comment #0853 submitted by Dallek).

¹⁴⁵ Varazo (Comment #0250).

¹⁴⁶ Pulido (Comment #0019); see also Shuval (Comment #0564) (“The [E]yeglass [R]ule is a beautiful and wonderful thing. Giving patients a copy of their prescription is essential.”).

¹⁴⁷ Burchell (Comment #0866). The FTC recognizes that the increase in online optical dispensaries may theoretically lead to reduced prescriber profits, but notes that the evidentiary record does not currently contain empirical evidence demonstrating this effect.

¹⁴⁸ *Id.*

increasing the potential for such prescribers to steer patients into purchasing eyeglasses in-house.¹⁴⁹

Opticians, in particular, expressed strong support for the automatic prescription release requirement, with the National Association of Optometrists and Opticians (“NAOO”), a trade association representing co-located optical dispensaries, characterizing the Rule as a “triumph of narrowly tailored government action that directly addresses [a] specific consumer problem with minimal cost and remarkable benefits.”¹⁵⁰ According to NAOO, any costs to prescribers from prescription release has been “trivial,” while benefits to consumers have been significant, allowing them to comparison-shop and choose the optical dispenser of their choice.¹⁵¹ This, in turn, according to the commenter, has helped foster exponential growth in the ophthalmic goods market.¹⁵² NAOO added that it was critical to maintain the automatic release requirement due to the continuing “imbalance of power between patient and prescriber,” and powerful financial incentives for prescribers—who sell the products that they prescribe—to keep sales in-house.¹⁵³

¹⁴⁹ Comment #0803 submitted by Couch.

¹⁵⁰ Comment #0748 submitted by Cutler; *see also, e.g.*, Ahrens (Comment #0022) (other opticians expressing support for automatic prescription release); Opticians Association of Alaska, Inc. (Comment #0852 submitted by Brand); Hoffman (Comment #0026).

¹⁵¹ Comment #0748 submitted by Cutler. The NAOO noted that based on member experience and observation, thousands of optometrists affiliated in co-location with their members comply with the Rule with “little or no added costs or other burden on the eye care practice.” *Id.*

¹⁵² *Id.*

¹⁵³ *Id.* NAOO noted that optometry and ophthalmology are among the very few health care professions in which prescribers also sell, and often derive a significant portion of their income from, the products they prescribe. *Id.*; *see also* note 66, *supra* (product sales typically account for 55 to 65 percent of optometrist revenue). In commenting on the CLR, however, the AOA pointed out that health care professionals in other areas—such as ambulatory surgery centers, orthopedic centers, and dental service

On the other hand, the AOA commented that, “[i]t is our understanding that doctors of optometry widely comply with the Rule,” and did not believe that compliance with the prescription release provision remains an issue.¹⁵⁴ The AOA also stated that patients are well informed of their ability to obtain their eyeglass prescriptions and have a greater expectation to receive their health information from their doctors as a result of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).¹⁵⁵ Accordingly, the AOA posited that “[g]iven that the requirements outlined in the Rule are now standard practice, it is questionable as to whether the Rule serves a continued benefit to patients.”¹⁵⁶ Nonetheless, the AOA did not expressly suggest modifying or terminating the prescription release provision, stating that the Rule, as currently drafted, is not necessarily harmful.¹⁵⁷ In addition, a few individual optometrists concurred that patients should be given their prescriptions after a refraction examination.¹⁵⁸

None of the commenters expressly proposed eliminating the prescription release requirement. Some prescribers, however, commented that requiring automatic release is unnecessarily burdensome and wasteful, since not all patients want paper copies of their prescription.¹⁵⁹ As one prescriber explained, “A lot of patients don’t want the copy and

providers, among others, also sell what they prescribe or recommend for treatment. AOA (CLR SNPRM Comment FTC-2019-0041-0096). The Commission acknowledged this fact. CLR Final Rule, 85 FR 50668, 50679-80 (stating that the Commission did not base its CLR amendments solely on a belief that contact lens prescribers’ role and market is necessarily unique, but rather considered the structure of the market as a contributing factor in an overall evaluation of the need for improved compliance and enforcement).

¹⁵⁴ Comment #0849 Submitted by Peele.

¹⁵⁵ Pub. L. 104-191 (Aug. 21, 1996); Comment #0849 submitted by Peele.

¹⁵⁶ Comment #0849 submitted by Peele.

¹⁵⁷ *Id.*

¹⁵⁸ *See, e.g.,* Kim (Comment #0667); Heuer (Comment #0670).

¹⁵⁹ Barnes (Comment #0043); Lunsford (Comment #0346).

we end up throwing the paper away. I sometimes worry that if a patient chose not to take it, we would later be accused of not offering it to them.”¹⁶⁰ Some commenters suggested that instead of automatically providing a copy, the Rule should require that prescriptions be made accessible electronically, or only upon request.¹⁶¹

6. Compliance With the Automatic Prescription Release Requirement

Commenters disagreed over whether most prescribers comply with the automatic prescription release requirement. As stated above, the AOA expressed its belief that doctors of optometry typically comply with the Rule.¹⁶² In addition, several individual prescribers asserted that they always give patients a paper copy of their prescription.¹⁶³ Other individual prescribers commented that all the prescribers they know do the same.¹⁶⁴ It should be noted, however, that prescribers may be aware in a general way of their obligation to release prescriptions and yet be ignorant of the precise requirements of the prescription release provision. For example, in some instances, prescribers may violate

¹⁶⁰ Barnes (Comment #0043).

¹⁶¹ Lunsford (Comment #0346); B.C. (Comment #0749).

¹⁶² Comment #0849 submitted by Peele.

¹⁶³ Johnson (Comment #0654); Michel (Comment #0472); Cook (Comment #0541); Kaulfuss (Comment #0570); McWilliams (Comment #0635); Brosman (Comment #0637). Numerous prescribers who commented on the Contact Lens Rule proposals also wrote that they consistently release prescriptions to patients after each eye examination—including examinations for eyeglass prescriptions—and attested that their colleagues do the same. *E.g.*, Carlson (CLR WS Comment FTC-2017-0099-0727) (“Each and every patient of mine gets their glasses and contact lens prescription at the end of their exam. It is not only the law but ethical.”); Chakuroff (CLR WS FTC-2017-0099-0763) (“Every patient I see is provided a copy of their glasses and contact lens prescriptions.”).

¹⁶⁴ Kanevsky (Comment #0364); Smith (Comment #0365); Hartenstein (CLR WS FTC-2017-0099-0766) (“The overwhelming majority of eye doctors already provide patients with copies of prescriptions for both glasses and contact lenses per your previous mandates.”); *see also* CLR SNPRM, 84 FR 24664, 24673.

the Rule by waiting for a patient to ask for the prescription, or asking a patient, “Do you want a copy of your prescription?” In both circumstances, the prescriber has violated the Rule since the prescription is not automatically provided. Indeed, a number of prescribers admitted to doing exactly that when commenting on the CLR, with many misstating the prescription release requirements and asserting that they always “offer” prescriptions to their patients or provide them “when requested,” rather than automatically providing prescriptions “whether or not requested by the patient,” as required under both the Contact Lens Rule and Eyeglass Rule.¹⁶⁵ Many prescribers may thus believe they are complying with the Rule even though they are not, and might also be incorrect in assessing, and reporting on, their own compliance and that of their colleagues.

A number of commenters, meanwhile, asserted that, even though the Rule has required, for more than four decades, that prescribers automatically release eyeglass prescriptions to their patients, prescribers still routinely fail to comply, either by failing to provide a prescription unless requested, requiring a waiver in exchange for a prescription, or failing to provide a prescription at all. According to eyeglass seller and manufacturer Warby Parker, “[i]t is well known in the industry that many [prescribers] refuse to give patients prescriptions unless they specifically request it, and some [prescribers] place

¹⁶⁵ See CLR SNPRM, 84 FR 24664, 24673-74. Staff is aware of similar prescriber comments in the context of eyeglass prescriptions. The Eyeglass Rule specifically mandates that patients be handed a copy of their prescriptions automatically without their asking for them. And while seemingly minor, the act of waiting for a patient to ask, or offering a prescription rather than automatically providing it, can put patients in an awkward position, since they may feel they are showing disloyalty to their prescriber if they want to shop for eyeglasses elsewhere. See Eyeglass II Report, *supra* note 26, at 271 (noting that according to commenters, consumers are not always comfortable requesting their prescription, and may be unwilling to risk offending their doctors). Such an act may therefore undermine the Rule’s intent to boost comparison-shopping and foster a vibrant marketplace.

intimidating and unnecessary warnings or waivers of responsibility on the prescriptions they do release.”¹⁶⁶

One commenter, an optician, opined that the practice of prescribers failing to automatically release prescriptions is “flagrant,”¹⁶⁷ while another commented that “[i]t has been my observance that the Eyeglass Rule is not being complied with at all.”¹⁶⁸ These two commenters asserted that prescribers often do not provide patients with prescriptions until after patients are led into the prescriber’s in-house optical dispensary,¹⁶⁹ a practice that would violate the Rule because the examination has concluded, and the patient should have already been provided with the prescription. And the NAOO commented that while it did not possess empirical evidence, “experiential and anecdotal evidence and observation of industry leaders indicates that while many consumers are getting a copy of their eyeglass prescription upon completion of the eye exam, some are not, and some are faced with resistance when they attempt to obtain their prescriptions.”¹⁷⁰

The Commission did not receive many comments from consumers specifically addressing the issue of prescription release in response to the ANPR. However, a number of consumers who commented during the CLR review stated that their prescribers failed

¹⁶⁶ Comment #0817 submitted by Kumar.

¹⁶⁷ Santini (Comment #0047) (“In my area, it is common for eye care providers who exam [sic] AND Sell glasses to not be forthcoming with providing the spectacle Rx, particularly when consumers demand it”).

¹⁶⁸ Tedesco (Comment #0042).

¹⁶⁹ *Id.*; Santini (Comment #0047); *see also* Opticians Association of Virginia (Comment #0647 submitted by Nelms).

¹⁷⁰ Comment #0748 submitted by Cutler.

to provide them with their prescriptions for contact lenses *and* for eyeglasses.¹⁷¹ And separate from these rule review processes, the Commission continues to receive consumer complaints about noncompliance with the automatic release provisions of both the Eyeglass Rule and Contact Lens Rule. In December 2020, the Commission sent warning letters to 28 prescribers after consumers complained to the FTC that the prescribers had violated the Eyeglass Rule.¹⁷² And in April 2016, the Commission sent warning letters to 45 contact lens prescribers after receiving complaints alleging the prescribers had violated the CLR by failing to release prescriptions.¹⁷³

¹⁷¹ *See, e.g.*, Nichols (CLR WS Comment FTC-2017-0099-0209) (said she was charged for her eyeglass prescription); Tennison (CLR WS Comment FTC-2017-0099-0453) (does not receive written prescriptions for lenses or eye glasses after exams); Bogner (CLR NPRM Comment FTC-2016-0098-1398); Rasczyk (CLR NPRM Comment FTC 2016-0098-1415); Strobel (CLR NPRM Comment FTC-2016-0098-1446); Austin (CLR NPRM Comment FTC-2016-0098-1514); Martinez (CLR NPRM Comment FTC-2016-0098-2090). A few other CLR consumer commenters, however, stated that although they do not receive their prescriptions after a contact lens fitting, they typically do receive them after a refraction exam for eyeglasses. *See, e.g.*, Hall (CLR WS Comment FTC-2017-0099-0227); Krainman (CLR NPRM Comment FTC-2016-0098-1373); Zeledon (CLR NPRM Comment FTC-2016-0098-1377).

¹⁷² Press Release, Fed. Tr. Comm’n, FTC Sends 28 Warning Letters Regarding Agency’s Eyeglass Rule (December 8, 2020), <https://www.ftc.gov/news-events/press-releases/2020/12/ftc-sends-28-warning-letters-regarding-agencys-eyeglass-rule>. Similarly, in May 2016, the Commission sent warning letters to 38 prescribers after receiving consumer complaints alleging violations of the Eyeglass Rule. Press Release, Fed. Tr. Comm’n, FTC Issues Warning Letters Regarding Agency’s Eyeglass Rule (May 13, 2016), <https://www.ftc.gov/news-events/press-releases/2016/05/ftc-issues-warning-letters-regarding-agencys-eyeglasses-rule>.

¹⁷³ Press Release, Fed. Tr. Comm’n, FTC Issues Warning Letters Regarding the Agency’s Contact Lens Rule (Apr. 7, 2016), <https://www.ftc.gov/news-events/press-releases/2016/04/ftc-issues-warning-letters-regarding-agencys-contact-lens-rule>. During the Commission’s CLR review, the AOA and several optometrists pointed out that based on a percentage of the total number of eye patients in the United States, the number of complaints to the FTC about prescribers’ failure to release prescriptions is quite small. *See* CLR Final Rule, 85 FR 50668, 50676; CLR SNPRM, 84 FR 24664, 24674. This is correct, but does not mean that the number of prescribers who fail to release prescriptions is correspondingly small. As discussed in some detail in the CLR SNPRM and CLR Final Rule, a lack of formal consumer complaints about failure to release prescriptions does not equate with prescriber compliance. Based on the Commission’s experience, the vast majority of injured or impacted consumers do not typically register complaints with the government, and even fewer are likely to file a formal complaint about a prescriber’s

Two commenters also submitted consumer survey evidence about prescriber compliance. Warby Parker submitted results from an October 2015 survey, conducted on the company's behalf by the polling firm SurveyMonkey, which reported that, of consumers who had purchased eyeglasses within the last three years, 47 percent of those who saw optometrists and 31 percent of those who visited ophthalmologists were not automatically provided with a physical copy of their eyeglass prescription.¹⁷⁴

Another commenter, contact lens seller 1-800 CONTACTS, cited a survey—conducted on its behalf by the firm Survey Sampling International (“SSI”) and submitted previously with a comment on the Commission’s Contact Lens Rule review—which found that only 34 percent of eyeglass wearers automatically received their prescriptions on the day of their office visit, with another 19 percent receiving it during their visit, but only after asking for it.¹⁷⁵ According to the SSI survey, some consumers were able to

failure to release their prescription. *See* CLR Final Rule, 85 FR 50668, 50676; CLR SNPRM, 84 FR 24664, 24674-75.

¹⁷⁴ Comment #0817 submitted by Kumar. The SurveyMonkey survey comprised 1,329 respondents recruited from a sample that was U.S. Census-balanced and representative of the national distribution of major demographic factors, including age, gender, geography, and income. Respondents were not informed of the identity of the survey sponsor. Survey respondents who had purchased eyeglasses within the last three years (65% of the total respondents) answered questions about prescription information, purchase behavior, and prescriber experience. Within the set of respondents who had purchased within the last three years, 54% had purchased within the last 12 months. There were no significant differences in responses regarding automatic prescription release between those who had purchased within the last year and those who had purchased between one and three years prior to the survey. The significant difference in automatic release compliance between optometrists and ophthalmologists may be due to the fact that fewer ophthalmologists sell eyeglasses, and might thus have less incentive to withhold a consumer’s prescription, but the survey did not directly explore this issue.

¹⁷⁵ Comment #0834 submitted by Williams. According to 1-800 CONTACTS, the data derive from an October 2015 SSI online survey of 303 prescription eyeglass wearers. *See* “FCLCA Study, Focus on Prescription (Rx),” attached as Exhibit B to 1-800 CONTACTS (CLR RFC Comment FTC-2015-0093-0555 submitted by Williams). Respondents were not informed of the identity of the survey sponsor. The Commission has some concerns about the methodology utilized for this survey, particularly about the lack of an “I don’t know” response option for some questions, but believes the

obtain their prescription at a later point by returning to their prescriber's office, but 39 percent of consumers never received their prescription at all.¹⁷⁶

The Commission has also reviewed five consumer surveys—submitted and considered during the CLR review—which found that between 21 and 34 percent of contact lens users did not receive their prescriptions after their exam and fitting.¹⁷⁷ These surveys asked only about receipt of contact lens prescriptions, not eyeglass prescriptions, and there are some differences in the examination and prescription processes.¹⁷⁸ But the

information may still be suggestive, particularly when viewed in conjunction with information from other sources and the absence of contradictory data.

¹⁷⁶ *Id.*

¹⁷⁷ The results from the individual consumer surveys are as follows: (1) June 2019 survey by Dynata on behalf of 1-800 CONTACTS of 1,011 contact lens users found that 21% said they never received their prescriptions (1-800 CONTACTS (CLR SNPRM Comment FTC-2019-0041-0135)); (2) January 2017 survey by Caravan ORC International on behalf of Consumer Action of 2,018 adults found that 31% of contact lens users said that at their last eye exam, their doctor did not provide them with a paper copy of their prescription (Consumer Action (CLR NPRM Comment FTC-2016-0098-2954)); (3) December 2016 survey of 1,000 contact lens users by SSI on behalf of 1-800 CONTACTS found that 24% of consumer respondents said they did not receive their prescription (1-800 CONTACTS (CLR NPRM Comment FTC-2016-0098-2738)); (4) May 2015 SSI survey of 2,000 contact lens wearers found that 34% said they did not receive their prescription (1-800 CONTACTS (CLR RFC Comment FTC-2015-0093-0555 submitted by Williams, Ex. C)); and (5) November 2014 SSI survey of 2,000 contact lens wearers found that 34% said they did not receive their prescription (1-800 CONTACTS (CLR RFC Comment FTC-2015-0093-0555 submitted by Williams, Ex. C)). As noted in the CLR SNPRM, the manner in which a few of the questions were phrased in the 2014 and 2015 surveys raised some Commission concerns, since some questions were leading, lacked an "I don't know" response option, and used a term—"hard copy"—which not all consumers may understand. The more recent surveys represented an improvement because they included an option for respondents to acknowledge that they do not recall whether they received their prescriptions, and used the term "paper copy" rather than "hard copy." CLR SNPRM, 84 FR 24664, 24672.

¹⁷⁸ A primary difference is that contact lens exams involve a lens "fitting," in which consumers try on the lenses, and prescriptions are only to be provided after the fitting is complete. Fittings can entail sending consumers home with a set of lenses to try out for a few days, and thus sometimes the prescriber will not provide the prescription until after this process. This sometimes leads consumers to think they should have been provided their prescriptions when, in fact, the fitting was not yet complete. There is no such fitting for eyeglass prescriptions. In theory, this should mean that fewer eyeglass patients are confused as to whether they did or did not receive their prescriptions when

mandatory prescription release requirements are similar, and there is little evidence in the record to indicate that prescribers provide eyeglass prescriptions in significantly greater numbers than they do contact lens prescriptions.¹⁷⁹

It is important to acknowledge that no survey is perfect, and all surveys are subject to methodological limitations, as well as limits commonly associated with survey evidence. The Commission has also recognized, however, that multiple surveys conducted by different sources at different times with similar results can bolster the credibility of each individual survey.¹⁸⁰ Furthermore, the Commission notes, as it did in the CLR Final Rule, that despite multiple opportunities and requests for comment since 2015, the Commission has yet to find or receive any reliable consumer-survey data rebutting or contradicting the submitted findings for either contact lens users or eyeglass wearers, or establishing (other than anecdotally) that consumers consistently receive their prescriptions from prescribers.¹⁸¹

Consumer behavior and third-party seller experience may also reveal the level of prescriber compliance with the automatic prescription release requirement. For example, comments submitted pursuant to the rulemaking process, and staff communications with

they were supposed to. The fact that the percentage of eyeglass users surveyed who said they did not receive their prescriptions is roughly the same as, or even higher than, that of contact lens wearers surveyed adds considerable credence to both types of surveys, and provides further support for the conclusion that a substantial number of consumers are not automatically receiving their prescriptions from prescribers as the Rule requires.

¹⁷⁹ As noted, *supra* note 171, a small number of consumer commenters to the CLR stated that although their prescribers fail to give them their contact lens prescriptions, they typically do provide them with their eyeglass prescription after each eye exam. *See, e.g.*, Hall (CLR WS Comment FTC-2017-0099-0227); Krainman (CLR NPRM Comment FTC-2016-0098-1373); Zeledon (CLR NPRM Comment FTC-2016-0098-1377). The Commission has not seen empirical data that supports this (and, in fact, it appears to be contradicted by the consumer survey data).

¹⁸⁰ *See* CLR Final Rule, 85 FR 50668, 50675; CLR SNPRM 84 FR 24664, 24673.

¹⁸¹ *See* CLR Final Rule, 85 FR 50668, 50675.

industry, indicate that many consumers who attempt to purchase eyeglasses from third parties do not present their prescriptions.¹⁸² These consumers must either request a copy of their prescriptions from their prescribers or request that the sellers do so.¹⁸³ This suggests that these consumers were not provided with a copy of their prescriptions as required by the Rule.¹⁸⁴

In terms of the scope of this issue, Warby Parker commented that it is required to expend substantial resources “persuad[ing prescribers] to provide the information required to fill a consumer order,” and that it informs between 50 and 100 consumers per day that it is unable to complete their eyeglass orders.¹⁸⁵ In addition, more than 20 consumers commented in this rule review that, when they tried to purchase eyeglasses, they asked their eyeglass sellers to obtain or verify the prescription with the prescribers, often without success.¹⁸⁶ Although this type of data does not allow the Commission to

¹⁸² See Warby Parker (Comment #0817 submitted by Kumar).

¹⁸³ According to Warby Parker (Comment #0817 submitted by Kumar), before it processes an order it verifies every prescription by viewing a copy of the prescription or speaking with the customer’s prescriber. In discussions with Warby Parker, the company has indicated that in 12 percent of all prescription eyewear orders (including both online and in-store orders), consumers utilize what is known as a “call doctor” request, whereby the customer requests that Warby Parker call the prescriber on behalf of the customer to obtain prescription information. However, the company noted that as of March 15, 2017, 15 percent of all “call doctor” requests Warby Parker made on behalf of its customers have been unanswered (*i.e.*, the prescriber has not provided the requested prescription information to Warby Parker). As a result, Warby Parker believes it may be more efficient for a customer to request the prescription information from the provider.

¹⁸⁴ It is reasonable to expect that if consumers possessed copies of their prescriptions, many would provide them to third-party sellers instead of asking the sellers to obtain their prescriptions from their prescribers. It is also possible, however, that some consumers could have received copies of their prescriptions but misplaced them, or simply thought it easier for the third-party seller to obtain copies of the prescription than to locate and provide the copies themselves in the format requested by the seller.

¹⁸⁵ Comment #0817 submitted by Kumar. Unlike with contact lenses, prescribers are not required by rule to verify eyeglass prescription requests from third-party sellers.

¹⁸⁶ See, *e.g.*, Debnam (Comment #0039); White (Comment #0053); Kidwell (Comment #0054); Averett (Comment #0057); Silva-Sadder (Comment #0065); Tresham

conclusively determine the level of prescriber compliance with automatic prescription release, or the number or percentage of consumers who might not have received a copy of their eyeglass prescription, it likely supports the finding that many patients are not automatically receiving a copy of their eyeglass prescriptions.

Lastly, it must be acknowledged that the same structural issue—an “inherent conflict of interest” in that prescribers sell the items they prescribe—that led the Commission to enact the Eyeglass Rule and CLR, and for Congress to enact the FCLCA,¹⁸⁷ and that the Commission cited as an ongoing factor in its decision to amend and strengthen the CLR,¹⁸⁸ still exists with respect to the eyeglass market and the Rule. According to some industry sources, eyeglass sales amount to approximately 37 to 44 percent of an optometric practice’s gross revenue, with gross profit on eyeglass sales in the area of 62 percent.¹⁸⁹ While many prescribers have noted that they follow medical ethical codes that require they prioritize their patients’ health,¹⁹⁰ it cannot be denied that

(Comment #0075); Ramiah (Comment #0139); Capurso (Comment #0149); Kulp (#0150); Lass (Comment #0197); Moran (Comment #0202); Wilbur (Comment #0215); Vieira (Comment #0237); Lavieri (Comment #0242); Donovan (Comment #0330); Panaccio (Comment #0340); Kingsley (Comment #0356); Gartland (Comment #0370); Gold (Comment #0340); Stout (Comment #0527); Crollini (Comment #0607). These commenters stated that their online orders were delayed, made more difficult, or defeated altogether, when their prescribers would not provide their prescription information.

¹⁸⁷ See H.R. Rep. No. 108-318, 108th Cong., 1st Sess. 4 (2003) at 4-5 (2003) (statements of Rep. W.J. Tauzin) (noting there is a “classic conflict of interest that robs the consumers of the ability to shop competitively for the best price”).

¹⁸⁸ CLR Final Rule, 85 FR 50668, 50678-80 (“Moreover, the existing regulatory structure in the U.S., which bars a consumer from obtaining contact lenses without a prescription while permitting prescribers to sell what they prescribe, creates regulatory-based economic incentives for some prescribers to not release prescriptions, or to not release them unless requested by the consumer.”).

¹⁸⁹ ECP University, “Key Metrics: Assessing Optometric Practice Performance & Best Practices of Spectacle Lens Management Report,” 25, 40-41; *see also* note 66, *supra*.

¹⁹⁰ AOA (Comment #0849 submitted by Peele). *See also* Leeper (CLR NPRM Comment FTC-2016-0098-0798); MacDonald (CLR NPRM Comment FTC-2016-0098-

it is contrary to prescribers' financial self-interest for their patients to take prescriptions elsewhere to buy eyeglasses.¹⁹¹

7. Evidence Regarding Consumers' Awareness of Their Right to Receive Their Prescription

As with the question of Rule compliance, there was little consensus among commenters as to whether consumers are fully aware of their right to their prescriptions.¹⁹² In its comment, the AOA asserted that patients are now well-informed of their ability to obtain their eyeglass prescriptions.¹⁹³ Other commenters disagreed, with some eyeglass sellers asserting that many patients are still not aware of the Rule and their rights.¹⁹⁴

In previous reviews of the Eyeglass Rule, the Commission received conflicting empirical evidence regarding the extent of consumer awareness, with some studies

1586); Aman (CLR NPRM Comment FTC-2016-0098-2523); Woo (CLR NPRM Comment FTC-2016-0098-2254); Talley (CLR RFC Comment FTC-2015-0093-0601).

¹⁹¹ This, of course, was the basis for the Eyeglass Rule in the first place. The Commission determined that there was a long documented history of prescribers taking action to prevent or discourage patients from buying eyeglasses from third parties. *See* Eyeglass I Rule, 43 FR 23992, 24003. Even apart from any intentional actions prescribers may engage in to flout the Rule, this financial self-interest may result in prescriber bias to steer patients to purchasing glasses in-house. As the Supreme Court has observed, “established ethical standards may blend with private anticompetitive motives in a way difficult even for market participants to discern. Dual allegiances are not always apparent to an actor.” *N.C. State Bd. of Dental Exam’rs v. FTC*, 574 U.S. 494, 505 (2015). While some prescribers may sincerely believe that, from a health perspective, it is in their patients’ best interest to obtain their eyeglasses from their prescriber, the Rule mandates that this decision belongs to the patient.

¹⁹² The Rule’s imposition of an obligation on a prescriber to automatically release an eyeglass prescription creates a corresponding right for consumers to receive it. *See* Eyeglass I Report, *supra* note 6, at 269 (“By requiring the release of the prescription in every case the public will have a clear, absolute right to their prescriptions.”).

¹⁹³ AOA (Comment #0849 submitted by Peele).

¹⁹⁴ Opticians Association of Virginia (Comment #0647 submitted by Nelms); NAOO (Comment #0748 submitted by Cutler); *see also* Warby Parker (Comment #0817 submitted by Kumar) (stating that many consumers are unaware of their rights and the Commission should try to increase awareness).

suggesting a relatively high degree of awareness,¹⁹⁵ and others indicating that consumers, particularly older patients, were unaware of their right to automatically receive a copy of their prescription.¹⁹⁶ For this review, none of the commenters submitted survey evidence specifically focused on consumer awareness of their right to their eyeglass prescription. One commenter, 1-800 CONTACTS, however, cited a survey submitted to the Commission during the Contact Lens Rule review which indicates that lack of awareness of a right to an eyeglass prescription is still an issue.¹⁹⁷ According to the survey, 49 percent of prescription eyeglass wearers are not aware that they have a right to receive a copy of their prescription, and 51 percent are not aware that their eye exam provider cannot charge for a copy of their prescription.¹⁹⁸

¹⁹⁵ See Eyeglass II Report, *supra* note 26, at 257-62 (citing Market Facts Study for the finding that a large majority of those surveyed knew they did not have to purchase eyeglasses from the examining doctor and could ask for an eyeglass prescription after an examination, although many mistakenly thought they had to ask for it, and some thought doctors were allowed to charge extra for providing it).

¹⁹⁶ See Presiding Officer's Report, *supra* note 33, at 22.

¹⁹⁷ See "FCLCA Study, Focus on Prescription (Rx)," attached as Exhibit B to 1-800 CONTACTS (CLR RFC Comment FTC-2015-0093-0555 submitted by Williams).

¹⁹⁸ *Id.* The manner in which the consumer awareness questions were phrased in the survey submitted by 1-800 CONTACTS did raise some concerns about the weight that should be accorded to the results. In particular, the questions were leading and used a term—"hard copy"—that some consumers might not understand. On the other hand, the question's phrasing may have led to under-reporting by consumers who in fact did not know their right, but did not want to admit that, because they did not want to acknowledge that they were unaware of their rights under federal law (this is known as social-desirability bias). See Diamond, *Reference Guide on Survey Research*, in Reference Manual on Scientific Evidence, 2nd. ed., 248-264 (Federal Judicial Center 2000), available at <https://wwws.law.northwestern.edu/faculty/fulltime/diamond/papers/referenceguidesurveyresearch.pdf>; Fowler, *How Unclear Terms Affect Survey Data*, The Public Opinion Quarterly (Summer 1992), available at <https://www.jstor.org/stable/2749171>; see generally, Carl A. Latkin, et al., *The relationship between social desirability bias and self-reports of health, substance use, and social network factors among urban substance users in Baltimore, Maryland*, 73 Addictive Behaviors 133-136 (2017) (social desirability bias is the tendency of survey respondents to answer questions in a manner that will be viewed favorably by others, and can skew survey results by over-reporting attitudes and behaviors that may be considered desirable attributes, while underreporting less desirable

Furthermore, multiple other consumer surveys examined during the Contact Lens Rule review indicate that a high percentage of consumers (46 to 60 percent, according to submitted data) do not realize they are entitled to receive their contact lens prescription,¹⁹⁹ and it is likely that many of these consumers are also unaware they are entitled to their eyeglass prescription.

8. Analysis of Evidence Regarding Automatic Prescription Release Provision

Having considered the evidence compiled thus far—including the comments, empirical surveys, ongoing pattern of consumer complaints and anecdotal reports, and relevant evidence submitted during the CLR review (and the Commission’s determinations in that regard), along with the industry’s documented history of failing to provide eyeglass prescriptions automatically even when obligated by state and federal law—in conjunction with the intent, purpose, and history of the Eyeglass Rule, the Commission believes that there is still a significant need for the automatic prescription release provision. The Commission also concludes that improving compliance with, and consumer awareness of, the provision is necessary to further the goals of the Rule.

Finally, the Commission sees a benefit—to both consumers and prescribers—in aligning

attributes). Social-desirability bias in this instance likely underestimates the number of patients unaware of their right to their prescription. In other words, the way the question was phrased could lead to results that make it appear that more patients are aware of their rights than is, in fact, the case. *See* “FCLCA Study, Focus on Prescription (Rx),” attached as Exhibit B to 1-800 CONTACTS (CLR RFC Comment FTC-2015-0093-0555 submitted by Williams) (One question was phrased, “Are you aware that it is your right under federal law, as a patient to receive a hard copy of your contact lens/eye glasses prescription from your eye exam provider?” and the other asked, “Are you aware of the following ... - Your eye exam provider cannot charge you for an actual hard copy of your prescription?”).

¹⁹⁹ CLR SNPRM, 84 FR 24664, 24675 (citing a Caravan ORC International survey submitted by Consumer Action (CLR NPRM Comment FTC-2016-0098-2954) and SSI survey submitted by 1-800 CONTACTS (CLR NPRM Comment FTC-2016-0098-2738)).

the prescription release requirements and practices for both eyeglass and contact lens prescriptions.

At the time of the Rule's initial implementation, the Commission determined that failure to release prescriptions was pervasive and widespread, and that this constituted an unfair act or practice under section 5.²⁰⁰ In subsequent Eyeglass Rule reviews, the Commission noted that despite the Rule, compliance remained a problem, and expressed concern that if the automatic release requirement were removed, more prescribers might return to the practice of refusing or failing to release prescriptions.²⁰¹ And while some commenters assert that automatic prescription release is now such standard practice that it would be adhered to even absent a rule, the weight of the evidence in this Rulemaking clearly favors retaining the automatic release requirement. Furthermore, the Commission notes that, when it relied on voluntary compliance in the past, compliance was poor.²⁰²

The Commission remains concerned that a lack of compliance with the Rule is still prevalent, and that removing the automatic prescription release requirement might further reduce the number of consumers who receive their prescriptions, whether automatically or on request. The Commission has not seen evidence suggesting that the structure of the market or financial incentives for prescribers have changed in such a way as to make the automatic prescription release requirement no longer necessary. Arguably, the incentive that prescribers have to steer patients to in-house optical dispensaries rather than giving patients their prescription remains the same, if not stronger,²⁰³ than when the

²⁰⁰ Eyeglass I Rule, 43 FR 23992, 23998.

²⁰¹ Ophthalmic Practice Rules, 69 FR 5451, 5453 (noting that in a 1989 rule review, the Commission had found "significant non-compliance," and finding that as of 2004, lack of compliance was still a problem).

²⁰² See note 9, *supra*.

²⁰³ See Section I.C, *supra*; see also Burchell (Comment #0866) (positing that online dispensaries will put increasing pressure on prescribers' profit margins); NAOO

Rule was first implemented. Moreover, the evidentiary record indicates that a significant percentage of prescribers still do not automatically provide a prescription. The evidence also suggests that many consumers are still not fully aware of their right to receive or obtain their prescription. Furthermore, the population of eyeglass wearers is not static, and large numbers of consumers become first-time wearers each year. The Commission thus concludes that many consumers cannot reasonably avoid prescribers' failure to automatically release prescriptions as required by the Rule. It is important that this be remedied, and that consumers are aware of, and receive the benefits of, their right to comparison-shop for eyeglasses.

The Commission also has not seen evidence that the automatic release provision imposes an unreasonable burden on prescribers, or that there is a substantial countervailing benefit that would result from eliminating the automatic release requirement. Indeed, while a few prescribers asserted it was wasteful or unnecessary,²⁰⁴ other commenters felt it was not a significant burden,²⁰⁵ and the AOA stated that the automatic release provision was not "harmful" to prescribers.²⁰⁶ The Commission previously concluded that the requirement enhances consumer choice among eyeglass

(Comment #0748 submitted by Cutler) (noting that optometrists still earn the majority of their revenue from selling eyewear they prescribe); Professional Opticians of Florida (Comment #0803 submitted by Couch) (noting a dramatic increase in the number of prescribers' offices that sell eyewear).

²⁰⁴ See Lunsford (Comment #0346) (waste of time and resources to provide each patient with a copy of his or her prescription); Barnes (Comment #0043) (a lot of patients don't want a copy and end up throwing it away).

²⁰⁵ NAOO (Comment #0748 submitted by Cutler) ("Based on NAOO member experience, the thousands of optometrists affiliated in co-location with NAOO member companies regularly comply with the Eyeglass Rule and the Contact Lens Rule with little or no added cost or other burden on the eye care practice.").

²⁰⁶ Comment #0849 submitted by Peele.

sellers at a minimal compliance cost to eye care prescribers.²⁰⁷ Moreover, since the automatic prescription release provision has been in existence since 1978, maintaining it as part of the Rule would not impose new costs on prescribers. By contrast, eliminating it for eyeglass prescriptions would create the potential for confusion amongst patients and prescribers alike, since the automatic prescription release requirement still applies to contact lens prescriptions.²⁰⁸

The Commission also concludes that the potential benefits of increasing the number of patients who receive their prescriptions automatically are substantial. These benefits include: increased patient flexibility and choice in comparison-shopping for eyeglasses; fewer disputes between consumers and prescribers; fewer requests from patients for a copy of their prescription, and arguably, fewer requests for a copy of, or a verification of, a prescription from third-party sellers of eyeglasses, which some prescribers find burdensome;²⁰⁹ and a reduction in costs and voided sales by third-party sellers.²¹⁰ The cumulative effect of increased compliance and consumer awareness would likely increase competition, lower costs, and improve convenience and flexibility for patients, sellers, and prescribers.

9. Proposals for Improving Compliance and Consumer Awareness

Having reached a determination that the automatic release provision should be retained, and that it would be beneficial to increase compliance with, and awareness of, the provision, the Commission now evaluates proposals for how best to achieve this goal.

²⁰⁷ See Ophthalmic Practice Rules, 69 FR 5451, 5453.

²⁰⁸ 16 CFR 315.

²⁰⁹ Cerri (Comment #0509); Kiener (Comment #0593); Bolenbaker (Comment #0633).

²¹⁰ See Sections I.B.1, IV.A.2, *supra*, and Sections IV.A.5, IV.C.1, *infra*.

a. Proposal to Increase Enforcement

Of the commenters who discussed the automatic prescription release provision, very few offered suggestions for amending the Rule to increase compliance with, or consumer awareness of, this provision.²¹¹ A few, however, suggested that the Commission should improve compliance by bringing more enforcement actions against prescribers who fail to automatically release prescriptions.²¹² Warby Parker, in particular, noted that Commission enforcement actions have been “virtually non-existent,”²¹³ and asserted that more aggressive enforcement would quickly increase both prescriber compliance and consumer awareness.²¹⁴ To assist the Commission in its enforcement, Warby Parker also suggested creating a more “user-friendly” online complaint process for consumers.²¹⁵

The Commission recognizes the need for increased enforcement of the automatic prescription release provision. Simply put, with the evidence in the Rulemaking showing significant noncompliance with this provision after 40 years, it is clear that more enforcement is necessary to improve industry adherence. In this regard, the absence of documentation often makes it difficult in an enforcement investigation to determine whether, in any particular case, a prescriber provided a patient with a prescription. The lack of documentation also makes it difficult to determine how many times, or how

²¹¹ One commenter, the Opticians Association of Virginia, suggested that prescribers should be “reminded” of their obligation to release prescriptions, although the comment did not specify how prescribers should be reminded. Comment #0647 submitted by Nelms.

²¹² Warby Parker (Comment #0817 submitted by Kumar); Professional Opticians of Florida (Comment #0803 submitted by Couch).

²¹³ Comment #0817 submitted by Kumar.

²¹⁴ *Id.*

²¹⁵ *Id.* This suggestion is discussed in Section VI, *infra*.

frequently, a particular noncompliant prescriber has violated the Rule. Instead, allegations and denials of non-compliance often become a matter of a patient's word against that of the prescriber, making violations difficult to prove. Commission staff first identified this issue in its Eyeglass II Report, where it explained that the automatic release requirement had not helped to avoid "evidentiary squabbles"—as the Commission had hoped it would²¹⁶—but instead had increased them, because whether or not a prescriber had released a prescription could not, in most cases, be ascertained by documentary evidence.²¹⁷ Accordingly, the Commission has brought only one enforcement action against an eyeglass prescriber for failure to comply with the automatic release provision.²¹⁸ The Commission believes that improvement in its ability to assess and verify compliance with the Rule's automatic prescription release requirements will increase its ability to monitor and enforce compliance.²¹⁹

²¹⁶ Eyeglass I Rule, 43 FR 23992, 23998.

²¹⁷ Eyeglass II Report, *supra* note 26, at 275-76.

²¹⁸ *United States v. Doctors Eyecare Ctr., Inc.*, No. 3:96-cv-01224-D (N.D. Tex. June 24, 1996). The complaint alleged that the eye care center only released prescriptions when patients asked for them, and included waivers of liability on patients when doing so. The prescriber paid a \$10,000 civil penalty and was enjoined from future violations of the Eyeglass Rule. *See* Press Release, Fed. Tr. Comm'n, Dallas Eyecare Center Agrees to Settle Charges That They Failed to Give Consumers Copies of Their Eyeglass Prescriptions (May 3, 1996), <https://www.ftc.gov/news-events/press-releases/1996/05/dallas-eyecare-center-agrees-settle-charges-they-failed-give>.

²¹⁹ Separately, the Commission does not believe it necessary to amend the Rule to explicitly state that violations of the Rule constitute a violation of the Federal Trade Commission Act, as some commenters have proposed. *See* Warby Parker (Comment #0817 submitted by Kumar); 1-800 CONTACTS (Comment #0834 submitted by Williams); *see also* Santini (Comment #0047) ("There should be clear penalties if consumers encounter resistance at any point [in] obtaining their spectacle Rx."). The existing language in § 456.2 of the Rule, in conjunction with the Commission's authority to prescribe the Ophthalmic Practice Rules under section 18 of the FTC Act, make it sufficiently clear that violations of the Rule are unfair acts or practices under section 5 of the FTC Act, and can be enforced as such. *See* 16 CFR 456.2; 15 U.S.C. 57a; 15 U.S.C. 45.

b. Proposal to Require an Eye Care Patients' Bill of Rights

Commenter Warby Parker proposed that the Rule be amended to require that prescribers provide patients with written notices informing them of their right to their prescription.²²⁰ According to the proposal, such notices would take the form of a “bill of rights” for eyeglass patients, notifying them of their rights under the Eyeglass Rule, including their right to receive their prescription free of charge and to purchase glasses from a provider of their own choosing.²²¹ Such a proposal, if implemented and complied with, might increase consumer awareness and, presumably, increase the percentage of patients who receive prescriptions from their providers. Providing the document would also remind prescribers and their staffs of their obligation to provide patients with their prescriptions, and would remind patients to ask for their prescriptions in the event that prescribers failed to provide them without request, as the Rule requires.

A bill of rights would also impose a relatively small burden upon prescribers, since they would only need to provide a brief, standard, pre-drafted form for each patient, and would not have to perform additional recordkeeping. On the other hand, patients already receive forms and other paperwork when they visit a prescriber, increasing the possibility that patients might not read or attend to the information in a bill of rights.

²²⁰ Warby Parker (Comment #0817 submitted by Kumar). Warby Parker proposed this written notice for the Contact Lens Rule as well ((CLR RFC Comment FTC-2015-0093-0578 submitted by Kumar), as did 1-800 CONTACTS (CLR RFC Comment FTC-2015-0093-0555 submitted by Williams) and Lens.com (CLR RFC Comment FTC-2015-0093-0666 submitted by Samourkachian).

²²¹ Warby Parker (Comment #0817 submitted by Kumar). The Commission has considered similar proposals in the past, including during the initial Eyeglass I rulemaking, when it was suggested that the prescription itself should include a notice declaring that it could be taken to any optical dispensary to have eyeglasses fabricated. At that time, the Commission and staff concluded that such a notice was unnecessary since advertising by opticians would likely make patients aware of their prescription's portability. *See* Eyeglass I Report, *supra* note 6, at 278; Eyeglass I Rule, 43 FR 23992, 23998.

Moreover, the Rule already requires that prescribers provide patients with copies of their prescriptions, and yet evidence indicates that prescribers do not always do so. Without some mechanism to ensure prescriber compliance with the new obligation to provide a bill of rights, the requirement might not provide material benefits. For example, under Warby Parker's proposal, patients would be given a copy of the bill of rights to take with them, but there would be no requirement that prescribers maintain records of their compliance. Therefore, the bill of rights proposal does not require the type of prescriber recordkeeping that would allow for better Rule monitoring and enforcement, and help resolve disputes between patients and prescribers over whether a prescription had been released. It is thus possible that adding a bill of rights requirement would impose an increased burden on prescribers without providing tangible, countervailing benefits to consumers or prescribers.

Many prescribers might also object to an eyeglass patient's bill of rights out of concern that it might impart the impression to consumers that prescribers are untrustworthy. Prescribers voiced numerous objections of this type during the CLR review when the Commission proposed including a sentence on a consumer acknowledgment of prescription stating, "I understand I am free to purchase contact lenses from the seller of my choice."²²² According to prescribers, such a statement implies that they have done something wrong.²²³ It seems likely prescribers would oppose an eyeglass patient's bill of rights for the same reason.

²²² See CLR SNPRM, 84 FR 24664, 24678-79.

²²³ *Id.*

In fact, a similar bill of rights proposal was put forth by commenters to the Contact Lens Rule²²⁴ and considered, and the Commission ultimately decided against adopting it for many of the reasons cited herein.²²⁵ In light of these considerations, the Commission does not propose amending the Rule to require that prescribers provide patients with a bill of rights.

c. Proposal to Require Signage

Some commenters proposed that one way to increase compliance with, and awareness of, the automatic release provision, would be to amend the Rule to require that prescribers post conspicuous signage in their offices informing patients of their right to their prescriptions.²²⁶ Such signage is currently required by state law in California.²²⁷

If adopted, such a requirement could provide some of the same benefits as a bill of rights by educating consumers and, presumably, might also increase the percentage of patients who receive their prescription from their provider. A sign could also serve as a reminder to patients to ask for their prescription in the event a prescriber fails to provide it. Furthermore, a sign would impose relatively little burden on prescribers, since it would only have to be posted once. Lastly, enforcing such a provision could be relatively straightforward, since the Commission could simply perform spot checks on prescribers' offices.

²²⁴ 1-800 CONTACTS (CLR RFC Comment FTC-2015-0093-0555 submitted by Williams); Lens.com (CLR RFC Comment FTC-2015-0093-0666 submitted by Samourkachian); *see* CLR NPRM, 81 FR 88526, 88532-33.

²²⁵ CLR NPRM, 81 FR 88526, 88532-33.

²²⁶ Tedesco (Comment #0042); Warby Parker (Comment #0817 submitted by Kumar).

²²⁷ Section 2554 of the California Business and Professions Code requires that each prescriber office post, in a conspicuous place, a notice informing patients that eye doctors are required to provide patients with a copy of their spectacle prescriptions upon completion of the exam, and that patients may take their prescription to any eye doctor or registered dispensing optician to be filled. Cal. Bus. & Prof. Code § 2554.

On the other hand, the Commission lacks evidence about the effects of California's signage requirement on automatic prescription release. It is unclear how many patients would notice a sign at prescribers' offices, particularly since many prescribers' offices already have numerous ads or other postings about various patient rights, requirements, and obligations. It is possible that in the context of prescribers' offices, a signage requirement would not be as effective in increasing consumer awareness as a requirement that consumers be handed or shown a specific document. A sign would also not require a prescriber, or the prescriber's staff, to interact with each patient about their prescription, so it would serve as less of a reminder for them to provide patients with their prescriptions. And while the Commission might be able to verify compliance with a signage requirement by performing spot checks at prescribers' offices, such visits would not reveal whether the prescribers' office was complying with the Rule's automatic prescription release provision. Moreover, since signage would increase prescription release only if more consumers see a sign and ask for their prescription, relying on signage essentially shifts the burden of prescription release compliance and enforcement to the consumer, an approach the Commission has repeatedly rejected in the past.²²⁸

During its review of the CLR, the Commission gave extensive consideration to the possibility of using signage, particularly as an alternative to some form of written acknowledgment of prescription from the patient.²²⁹ The Commission ultimately decided against a signage provision, after determining that the benefits were limited and that requiring signage would be significantly less effective at ensuring contact lens

²²⁸ See Eyeglass I Rule, 43 FR 23992, 23998; Eyeglass II Rule, 54 FR 10285, 10286-87, 10303, 10313 & nn.180 & 181; *see also* Eyeglass II Report, *supra* note 26, at 255-58 (reporting the Market Facts Study results).

²²⁹ See CLR NPRM, 81 FR 88526, 88534; CLR SNPRM, 84 FR 24664, 24679; CLR Final Rule, 85 FR 50668, 50684-85.

prescription release than requiring a written patient confirmation.²³⁰ The Commission reaches the same conclusion with respect to proposed signage reminding consumers about their eyeglass prescriptions.²³¹

d. Proposal to Require a Confirmation of Prescription Release

Having determined that some type of documentation is necessary to increase adherence and improve enforcement of the Rule, the Commission next turns to consider what type of documentation should be required.

In 2020, the Commission amended the Contact Lens Rule to add a requirement that prescribers retain documentation confirming that they released contact lens prescriptions to patients as required by the CLR.²³² The CLR's confirmation requirement was adopted subsequent to the publication of the ANPR, and while none of the commenters to the ANPR explicitly proposed a signed acknowledgment, commenters to the CLR review made such a suggestion, and the Commission ultimately determined there would be substantial benefits to such an approach. In promulgating the requirement, the Commission stated its belief that the confirmation requirement would increase compliance with prescription release requirements and awareness of the CLR's requirements among consumers by mandating that prescribers present a document for patients to sign confirming that they received their prescription at the end of their contact lens fitting.²³³

²³⁰ CLR Final Rule, 85 FR 50668, 50685.

²³¹ The Commission further notes that imposing a signage requirement for eyeglass prescriptions, where one does not exist for contact lens prescriptions, could result in confusion for both consumers and prescribers.

²³² See CLR Final Rule, 85 FR 50668, 50687-88; 16 CFR 315.3(c).

²³³ See CLR Final Rule, 85 FR 50668, 50687-88.

The Confirmation of Prescription Release provision added to the CLR in 2021 requires prescribers do one of the following:

- (A) Request that the patient acknowledge receipt of the contact lens prescription by signing a separate statement confirming receipt of the contact lens prescription;
- (B) Request that the patient sign a prescriber-retained copy of a contact lens prescription that contains a statement confirming receipt of the contact lens prescription;
- (C) Request that the patient sign a prescriber-retained copy of the sales receipt for the examination that contains a statement confirming receipt of the contact lens prescription; or
- (D) If a digital copy of the prescription was provided to the patient (via methods including an online portal, electronic mail, or text message), retain evidence that such prescription was sent, received, or made accessible, downloadable, and printable.²³⁴

In order to relieve prescribers of the burden of crafting their own confirmation language, the CLR provides sample language for options (A), (B), and (C), but also allows prescribers to create their own wording for the signed confirmation if they so desire.²³⁵ Prescribers are required to maintain records or evidence of consumer confirmation, or that a digital copy was provided to the patient, for at least three years.²³⁶ Lastly, in order to limit the burden as much as possible, the CLR confirmation requirement only applies to prescribers with a financial interest in the sale of contact lenses.²³⁷

²³⁴ 16 CFR 315.3(c).

²³⁵ *Id.* at 315.3(c)(1)(ii).

²³⁶ *Id.* at 315.3(c)(2).

²³⁷ *Id.* at 315.3(c)(3).

The Commission believes a similar requirement for eyeglass prescriptions would have many benefits. A signed patient confirmation of release for eyeglass prescriptions would notify and remind consumers of their prescription portability rights and, in all likelihood, increase the percentage who receive their prescription from the prescriber. Providing the confirmation document, and obtaining the patient's signature, would remind prescribers and their staffs to provide prescriptions, and remind patients who might have received a confirmation document (and are asked to sign) but did not receive their prescription to ask for it.

Since the document is given to the patient, and the patient asked to sign it, such a document is less likely to go unnoticed or unread by patients than a bill of rights or office signage reminding patients of their prescription rights. And requiring prescribers to retain a signed confirmation would improve the Commission's ability to verify whether prescribers had complied with the Rule's requirement to release prescriptions to their patients. It would reduce the number of instances where a filed complaint simply pits the patient's word against that of the prescriber. Prescribers would also have valuable documentation to present in their defense should a patient lose or dispose of his or her prescription copy and mistakenly believe the prescriber had not provided it, a scenario cited by at least one commenter.²³⁸ In short, a confirmation of release would eliminate certain evidentiary problems related to Rule enforcement, one of the reasons the Commission adopted automatic prescription release when it promulgated the Eyeglass Rule in the first place.²³⁹ Ultimately, adding a confirmation of release requirement should result in more consumers having a copy of their prescriptions, and thus improve

²³⁸ Barnes (Comment #0043) ("I sometimes worry that if a patient chose not to take [the prescription], we would later be accused of not offering it to them."). Prescribers have also verbally informed Commission staff about such occurrences when responding to warning letters about failure to release prescriptions.

²³⁹ Eyeglass I Rule, 43 FR 23992, 23998.

consumer flexibility and choice, reduce the number of eyeglass sellers and consumers who call prescribers to obtain patient prescriptions, improve competition in the market for eyeglasses and frames, and lower prices for consumers.²⁴⁰

The primary drawback to requiring a signed confirmation is the increased recordkeeping burden imposed on prescribers, since they would have to provide the piece of paper and retain the signed form for a certain period of time.²⁴¹ This recordkeeping burden could be reduced to the extent that prescribers have adopted electronic medical record systems, especially those where patient signatures can be recorded electronically and inputted automatically into the electronic record. Furthermore, prescribers could scan signed paper copies of the confirmation and store those forms electronically to lower their compliance costs. Moreover, the added paperwork requirement may apply only to prescribers who use a separate form to get the patient's signed confirmation, since those who opt to add the confirmation to a copy of the patient's prescription or sales receipt would, presumably, be maintaining those records anyway. Prescribers also will likely have an established means of collecting patient confirmations and maintaining records for the purpose of complying with the CLR. The marginal cost of adopting such forms and systems to include eyeglasses prescriptions is likely to be very low. Accordingly, the Commission believes that any recordkeeping burden would be relatively minimal and outweighed by the benefits described above.

One concern is the possibility that requiring consumers to sign a confirmation that they received their prescription will sow doubts about prescriber integrity, and sully the

²⁴⁰ In addition, adding a Confirmation of Prescription Release requirement to the Eyeglass Rule would apply similar requirements to both eyeglass and contact lens prescription release, and would thus avert consumer and prescriber confusion about when patients had to sign a confirmation of prescription release.

²⁴¹ Prescribers who choose to offer a digital copy of the prescription would avoid this aspect of recordkeeping for those patients who consent to receive a digital copy.

doctor-patient relationship.²⁴² The Commission believes this to be unlikely. Consumers are accustomed to signing acknowledgments or receipts.²⁴³ Many pharmacists require patients to acknowledge that they do not have questions upon receiving a prescription; physicians' offices require visitors to sign in; and patients are accustomed to signing HIPAA acknowledgment forms signifying they received a provider's Notice of Privacy Practices ("NPP").²⁴⁴ The Commission is not aware of evidence that such requirements sow distrust on the part of the person signing the receipt. The Commission believes this will hold true for a Confirmation of Prescription Release for eyeglass prescriptions, particularly since prescribers can devise their own language of confirmation, and since

²⁴² The Commission considered this concern during its review of the CLR (CLR Final Rule, 85 FR 50668, 50680-81) and came to the conclusion that this concern is not significant enough to change the result.

²⁴³ This fact was also considered in the CLR evaluation. *Id.*

²⁴⁴ The U.S. Department of Health & Human Services ("HHS") proposed eliminating the requirement to obtain an individual's written acknowledgment of receipt of the provider's NPP, but patients have had experience signing such acknowledgements for many years. *See* Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446, 6485 (Jan. 1, 2021). As explained in the CLR, the impetus for the NPP signed acknowledgment and that for the CLR (and Eyeglass Rule) prescription release confirmation were very different, and—in contrast to eye prescriptions—there is little evidence that providers were not providing patients with their NPPs, and thus significantly less need for a patient acknowledgment of receipt. CLR Final Rule, 85 FR 50668, 50684-85 (noting that the primary intent of the HIPAA signed-acknowledgment was to provide patients an opportunity to review the provider's Notice of Privacy Practices, discuss concerns related to their private health information, and request additional confidentiality, not to remedy a lack of compliance, and that the HHS record does not contain empirical evidence showing that doctors are not fulfilling their obligations to provide Notices of Privacy Practices to patients); *see also* Request for Information on Modifying HIPAA Rules to Improve Coordinated Care, Office for Civil Rights, Department of Health and Human Services, 83 FR 64302, 64308 (Dec. 14, 2018) (discussing the intent of the HIPAA signed acknowledgment); *see also generally* Comments in Response to Request for Information on Modifying HIPAA Rules to Improve Coordinated Care, Office for Civil Rights, Department of Health and Human Services, <https://www.regulations.gov/document/HHS-OCR-2018-0028-0001>.

prescribers will already be obtaining patients' signatures from those who obtain contact lens prescriptions.

10. The Commission's Proposal to Require a Signed Confirmation of Prescription Release

After consideration of the evidence and proposals, the Commission proposes to amend the Rule to add a Confirmation of Prescription Release requirement. The Commission believes such a provision will increase the number of patients who receive their prescriptions, inform patients of the Rule and their right to their prescriptions, reduce the number of seller requests to prescribers for eyeglass prescriptions, improve the Commission's ability to monitor overall compliance and target enforcement actions, reduce evidentiary issues, complaints, and disputes between prescribers and consumers, and bring the Eyeglass Rule into congruence with the Confirmation of Prescription Release requirement of the Contact Lens Rule.²⁴⁵ The addition of a patient confirmation requirement accomplishes the desired objectives of the Rule with little increased burden on prescribers.

The Commission therefore proposes to amend § 456.3 to add the requirement that upon completion of a refractive eye examination, and after providing a copy of the prescription, the prescriber shall do one of the following:

- (i) Request that the patient acknowledge receipt of the prescription by signing a separate statement confirming receipt of the prescription;
- (ii) Request that the patient sign a prescriber-retained copy of a prescription that contains a statement confirming receipt of the prescription;

²⁴⁵ Should a prescriber wish to create a single document confirming receipt of both an eyeglass and a contact lens prescription (in cases where both prescriptions are finalized at the same time), the Commission believes such a document could meet the requirements of both rules so long as there are separate statements and signature lines for the contact lens prescription and the eyeglass prescription. Such a practice could help prescribers reduce any burden associated with confirmations.

- (iii) Request that the patient sign a prescriber-retained copy of the sales receipt for the examination that contains a statement confirming receipt of the prescription; or
- (iv) If a digital copy of the prescription was provided to the patient (via methods including an online portal, electronic mail, or text message), retain evidence that such prescription was sent, received, or made accessible, downloadable, and printable.

If the prescriber elects to confirm prescription release via paragraphs (i), (ii), or (iii), the prescriber may, but is not required to, use the statement, "My eye care professional provided me with a copy of my prescription at the completion of my examination" to satisfy the requirement. In the event the patient declines to sign a confirmation requested under paragraphs (i), (ii), or (iii), the prescriber shall note the patient's refusal on the document and sign it. A prescriber shall maintain the records or evidence of confirmation for not less than three years. Such records or evidence shall be available for inspection by the Federal Trade Commission, its employees, and its representatives. The prescription confirmation requirements shall not apply to prescribers who do not have a direct or indirect financial interest in the sale of eye wear, including, but not limited to, through an association, affiliation, or co-location with an optical dispenser.

The full text of the proposed Rule amendment is located at the end of this document.

B. Other Issues Surrounding Patients' Access to Eyeglass Prescriptions

1. Prescriber Responsibilities to Provide Additional Copies of Prescriptions

The Eyeglass Rule requires an ophthalmologist or optometrist to provide "one copy" of the patient's prescription immediately after the completion of the eye exam.²⁴⁶ In the ANPR, the Commission sought comment on whether it should amend the Rule to

²⁴⁶ 16 CFR 456.2(a).

require prescribers to provide duplicate copies of prescriptions to patients who no longer have access to the original.²⁴⁷ Patients may need an additional copy because they lost or misplaced their prescriptions, or because the prescription was not returned after they ordered eyeglasses.²⁴⁸ The Commission believes that there is often a valid need for consumers to obtain additional copies of their prescriptions, and encourages prescribers to provide them when requested. However, in a previous Rule review, the Commission considered this issue and determined not to mandate a requirement to provide additional copies since it did not receive sufficient evidence indicating that the practice of refusing to release additional copies of eyeglass prescriptions was prevalent.²⁴⁹ After reviewing the evidence in the instant rulemaking record, the Commission, for this same reason, declines to amend the Rule to require prescribers to provide patients with additional copies of eyeglass prescriptions upon request.

Optometrists, opticians, consumers, a consumer advocate, an online seller, and a telehealth prescriber commented in favor of amending the Rule to require that prescribers provide additional copies of prescriptions to patients that do not currently have access to their prescription.²⁵⁰ The NAOO stated its belief that, although optometrists affiliated

²⁴⁷ Eyeglass Rule ANPR, 80 FR 53274, 53276.

²⁴⁸ The Commission distinguishes a request for an additional copy of a prescription from a request for an initial copy of a prescription in instances when a consumer did not receive the prescription immediately after the completed eye examination. In the latter event, the prescriber must provide a copy of the prescription without a fee unless the prescriber did not release the prescription immediately following the examination because the patient failed to pay for the examination and the prescriber requires immediate payment from all patients, whether or not the exam reveals a need for ophthalmic goods. *See* 16 CFR 456.2(a).

²⁴⁹ *See* Eyeglass II Rule, 54 FR 10285, 10303.

²⁵⁰ DeMuth Jr. (Comment #0055); Ellis (Comment #0189); Prevent Blindness (Comment #0385 submitted by Parry); Schwartz (Comment #0514); Burchell (Comment #0866); Kiener (Comment #0593); Opticians Association of Virginia (Comment #0647 submitted by Nelms); NAOO (Comment #0748 submitted by Cutler); Pulido (Comment #0019); Professional Opticians of Florida (Comment #0803 submitted by Couch); Warby

with its member companies provide additional copies upon request at no charge, the Rule should clarify that consumers always have a right to their eyeglass prescriptions as part of their medical records.²⁵¹ It pointed out that, although consumers already have a right to their prescriptions under HIPAA, the 30-day period allotted to prescribers (and other covered entities) for the production of medical records under HIPAA is overly long for consumers who may need replacement eyeglasses.²⁵² Warby Parker commented that providing an additional copy furthers the original goal of the Rule to foster comparison-shopping in that it ensures that patients have the freedom to choose where to purchase their eyeglasses.²⁵³ Visibly, formerly known as Opternative, a telehealth prescriber, stated that such a requirement would be consistent with the Rule's intent and furthers its purpose.²⁵⁴ Warby Parker also stated that some prescribers refuse to provide such copies and that others charge patients for them.²⁵⁵ One commenter stated that there is no real

Parker (Comment #0817 submitted by Kumar); Stuart (Comment #0841); Opternative (now Visibly) (Comment #0853 submitted by Dallek).

²⁵¹ Comment #0748 submitted by Cutler; *see also* Prevent Blindness (Comment #0385 submitted by Parry) (calling the right to one's own prescription a "basic consumer right"); Professional Opticians of Florida (Comment #0803 submitted by Couch) (stating it is a consumer's right to have access to his or her prescription).

²⁵² Comment #0748 submitted by Cutler. In 2021, HHS proposed modifying the HIPAA Privacy Rule "to require that access [to protected health information] be provided 'as soon as practicable,' but in no case later than 15 calendar days after receipt of the request, with the possibility of one 15 calendar-day extension." Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446, 6459. The Cures Act Final Rule, implementing the 21st Century Cures Act, also requires healthcare providers to make certain classes of data available to patients in their electronic health records. *See* Section IV.B.2.b, *infra*. This may result in consumers having greater access to their refraction measurements.

²⁵³ Comment #0817 submitted by Kumar.

²⁵⁴ Comment #0853 submitted by Dallek. Several consumers also wrote in support of adding this requirement to the Rule. DeMuth, Jr. (Comment #0055); Ellis (Comment #0189).

²⁵⁵ Comment #0817 submitted by Kumar.

impact on a prescriber's business to provide a duplicate copy, while it allows consumers access to their prescription without needing to undergo a new exam.²⁵⁶ Some commenters stated the prescriber should have to release additional copies, but suggested that prescribers should be able to impose a small administrative fee.²⁵⁷ One commenter who supported permitting the imposition of a small fee explained that such a fee is justified because the prescriber faces a burden in providing the additional copy, and consumers should bear (or share) the responsibility for not having safeguarded the original copy they received following their examination.²⁵⁸ The NAOO stated that additional copies should be provided without requiring that patients file formal HIPAA requests and at no charge because the cost to the prescriber is trivial.²⁵⁹

Other commenters, including the AOA and the AAO, opposed amending the Rule to require that prescribers provide additional copies upon request.²⁶⁰ These commenters stated that most prescribers already provide additional copies at no charge and, therefore,

²⁵⁶ Jozwik (Comment #0002).

²⁵⁷ Kiener (Comment #0593); Pulido (Comment #0019); *see also* Burchell (Comment #0866) (stating administrative charge should reflect the cost of the paper, other office supplies, and office staff time; suggesting that current market supports a fee of \$2-\$10; and clarifying the fee should not be a profit-making mechanism). One commenter recommended that the Rule mandate prescribers provide one replacement copy at no charge, but permit a charge for subsequent copies. Stuart (Comment #0841).

²⁵⁸ Burchell (Comment #0866).

²⁵⁹ Comment #0748 submitted by Cutler. The HHS' proposed modifications to the HIPAA Privacy Rule would clarify that providers may not charge individuals a fee to inspect their protected health information in person (including when they photograph or record the information themselves) or to view and capture an electronic copy of their information via an internet-based method. Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446, 6465-6466.

²⁶⁰ *See, e.g.*, AAO (Comment #0864 submitted by Haber); AOA (Comment #0849 submitted by Peele); Publi (Comment #0040); Haas (Comment #0359); Sharma (Comment #0609); Berry (Comment #0673).

there is no need to mandate it by rule.²⁶¹ Some commenters stated that consumers should be responsible for copying and maintaining their prescription,²⁶² and that prescribers should not have to shoulder the burden of consumers who are remiss at recordkeeping.²⁶³ The AOA expressed concern with the possible health effects to consumers that could result from requiring prescribers to provide prescriptions long after an initial refraction, and stated that prescribers must be allowed to use their clinical judgment to determine whether it is medically appropriate to provide subsequent copies of a prescription that may not be recent.²⁶⁴ The organization did not detail specific negative health effects, but stated that there are scenarios wherein an optometrist may not want to reissue an eyeglass prescription to a patient. For example, the optometrist may have performed a more recent comprehensive eye exam that renders the previous prescription no longer appropriate, or the prescriber may be aware of other health changes for the patient that could necessitate a change in the prescription.²⁶⁵ The AOA also pointed out, as a comparison, that medical doctors are not required to give patients multiple copies of pharmaceutical prescriptions upon request and that some medical doctors may require payment for such additional copies.²⁶⁶

²⁶¹ AAO (Comment #0864 submitted by Haber); AOA (Comment #0849 submitted by Peele); Sharma (Comment #0609); Berry (Comment #0673). The AAO stated that if practices are inflexible with regard to providing duplicate copies, patients will go elsewhere for their eye care needs. Comment #0864 submitted by Haber. One commenter indicated that amending the Rule is not necessary because consumers should have access to their prescriptions through electronic health records or patient portals. Bolenbaker (Comment #0633).

²⁶² Publi (Comment #0040); Haas (Comment #0359).

²⁶³ *See, e.g.*, Haas (Comment #0359).

²⁶⁴ Comment #0849 submitted by Peele.

²⁶⁵ *Id.*

²⁶⁶ *Id.*

a. Analysis of Whether to Require Provision of Additional Copies of Prescriptions Upon Request

It is unnecessary to decide whether failure to provide an additional copy of a prescription upon request is an unfair act or practice because the Commission has not been presented with, and is unaware of, evidence that refusing to provide duplicate copies of prescriptions upon request is a prevalent problem. The NAOO, the AAO, and the AOA commented that prescribers do provide additional copies of prescriptions upon request.²⁶⁷ The only commenter who asserted that prescribers are not releasing duplicate copies of prescriptions upon request was Warby Parker.²⁶⁸ In support of its statement that some of its customers are being denied additional copies of prescriptions, Warby Parker cited to a survey that it said showed that 30 percent of consumers were not offered a copy of their prescription.²⁶⁹ This fact, however, may relate to the failure to initially release prescriptions to consumers, not the provision of additional copies, and thus does not establish that prescribers are refusing to provide additional copies to consumers upon request. Since the rulemaking record does not support a showing of prevalence, which is necessary for any Eyeglass Rule amendment,²⁷⁰ the Commission does not believe it has sufficient evidence to propose amending the Rule to require that prescribers provide additional copies of prescriptions upon request.²⁷¹

²⁶⁷ NAOO (Comment #0748 submitted by Cutler); AAO (Comment #0864 submitted by Haber); AOA (Comment #0849 submitted by Peele); *see also* Sharma (Comment #0609) (stating duplicates already being provided on voluntary basis); Berry (Comment #0673) (same).

²⁶⁸ Comment #0817 submitted by Kumar.

²⁶⁹ *Id.*

²⁷⁰ *See* 15 U.S.C. 57a(b)(3).

²⁷¹ The Commission recognizes that this result differs from the FCLCA and the CLR, which require prescribers to respond to requests for additional copies of prescriptions. 15 U.S.C. 7601(a)(2); 16 CFR 315.3(a)(2). *See also* CLR NPRM, 81 FR 88526, 88536 (explaining Act and Rule's requirements to provide a copy of an additional

**b. Analysis of Whether to Permit Prescribers to Charge Fees
for Provision of Additional Copies of Prescriptions**

In addition to not requiring that prescribers provide additional copies of prescriptions, the Eyeglass Rule does not set forth whether or not prescribers are permitted to charge for providing such copies. Some of the commenters requested the Commission amend the Rule to either permit a prescriber to charge a fee,²⁷² or to prohibit a prescriber from charging a fee,²⁷³ for providing additional copies. Since the Commission determined not to propose amending the Rule to require prescribers provide additional copies, it is unnecessary to address the issue of fees for mandated duplicate copies.²⁷⁴

In the current Rule review, as noted above, little evidence was placed on the record indicating that prescribers are not providing duplicate prescriptions upon request or that prescribers are charging more than nominal, administrative fees for providing additional copies of prescriptions. As a result, the Commission has not been presented with evidence that these practices are prevalent and does not believe an amendment

contact lens prescription upon request). However, as previously explained, the authority for the Eyeglass Rule is different than for the CLR, and requires a showing that the problem is prevalent.

²⁷² Kiener (Comment #0593) (proposing a small administrative fee); Burchell (Comment #0866) (stating administrative charge should reflect the cost of the paper, other office supplies, and office staff time; suggesting that current market supports a fee of \$2-\$10; and clarifying the fee should not be a profit-making mechanism); Pulido (Comment #0019) (proposing a small fee).

²⁷³ NAOO (Comment #0748 submitted by Cutler); Warby Parker (Comment #0817 submitted by Kumar). One commenter recommended that the Rule mandate prescribers provide one replacement copy at no charge, but permit a charge for subsequent copies. Stuart (Comment #0841).

²⁷⁴ As noted above, if the prescriber has failed to provide a copy of the prescription following the completed examination in violation of the Rule, the prescriber must provide a copy of the prescription when a patient later asks for it. Because the prescriber could not charge a fee had he or she provided it immediately following the examination, the prescriber may not do so in response to that patient's later request for an initial copy.

prohibiting or limiting the imposition of fees for additional copies of prescriptions is necessary.

2. Electronic Delivery of Prescriptions as a Means for Automatic Prescription Release Under § 456.2(a)

As previously noted, § 456.2(a) of the Eyeglass Rule provides that it is an unfair act or practice for a prescriber to fail to provide to the patient one copy of the patient's prescription immediately after the eye examination is completed. The Rule does not expressly permit electronic delivery of prescriptions as a means for automatic prescription release. The Commission believes expressly permitting electronic delivery in certain circumstances could provide benefits to consumers.

In 2021, the CLR was amended to allow prescribers to satisfy the CLR's automatic release requirement by providing the patient with a digital copy of his or her contact lens prescription, such as by text message, electronic mail, or an online patient portal, in lieu of a paper copy, provided the prescriber first identified the specific method of delivery to be used and obtained the patient's verifiable affirmative consent to this method of delivery.²⁷⁵ In the CLR SNPRM, the Commission noted that providing patients with an electronic copy of their prescription could enable patients to share prescriptions more easily with sellers when purchasing eyewear, and this in turn could potentially reduce the number of patient and seller requests for verification or additional copies of the prescription. To enhance portability, the Commission noted that electronic delivery methods should allow patients to download, save, and print the prescription.²⁷⁶

As discussed above, the Commission is proposing to amend the Rule to add a Confirmation of Prescription Release requirement.²⁷⁷ The proposed text of the Rule

²⁷⁵ CLR Final Rule, 85 FR 50668, 50717.

²⁷⁶ CLR SNPRM, 84 FR 24664, 24668.

²⁷⁷ See Sections II.A, IV.A.6, *supra*.

would provide prescribers with four alternative means of complying with the Confirmation of Prescription Release requirement. The fourth option states, “If a digital copy of the prescription was provided to the patient (via methods including an online portal, electronic mail, or text message), retain evidence that such prescription was sent, received, or made accessible, downloadable, and printable.” In order to allow prescribers to meet the Confirmation of Prescription Release requirement in this way, the Rule must describe the conditions under which electronic delivery of the prescription will satisfy the automatic prescription release requirements. The Commission therefore proposes to define the phrase, “provide to the patient one copy,” which appears in § 456.2(a) and creates the requirement to automatically release the prescription immediately after the eye examination is completed.²⁷⁸ This new definition expressly permits electronic delivery in certain circumstances.

a. The Commission’s Proposal to Add a Definition to § 456.1 to Permit Electronic Delivery of the Patient’s Prescription

Accordingly, the Commission proposes to modify the Rule by adding a definition of the term “provide to the patient one copy.” The Commission proposes to require that prescribers provide patients with either a paper copy of their prescription or, with the patient’s verifiable affirmative consent, a digital copy of the patient’s prescription in lieu of a paper copy. Verifiable affirmative consent means that a patient must have provided his or her consent to the prescriber in a way that can be later confirmed, such as through a signed consent form or an audio recording. The consent must also identify the specific method or methods of electronic delivery to be used because it is possible that a patient may prefer one method of electronic communication, but not others, and the patient should be able to make an informed choice.

²⁷⁸ 16 CFR 456.2(a).

Prescribers would be required to keep a record or evidence of a patient's affirmative consent for a period of not less than three years, which would facilitate Commission enforcement efforts to monitor compliance with the Rule. As the Commission concluded in the CLR Final Rule, the burden of retaining a record of patient consent should be minimal, "since prescribers who opt for electronic delivery of prescriptions will, in all likelihood, obtain and/or store such consent electronically."²⁷⁹ At any rate, obtaining and storing a record of patient consent should not take longer than obtaining and storing a patient's Confirmation of Prescription Release under option (i), (ii), or (iii), and prescribers choosing to use the fourth option to confirm prescription release would not need to collect additional information from the patient beyond the consent to electronic delivery. Finally, offering a prescription in a digital format would be an option for prescribers, but is not mandatory, so prescribers can choose not to offer electronic delivery of prescriptions if they find the recordkeeping provision overly burdensome.

The amended Rule would also require that if the prescription is provided electronically, it must be in a digital format that can be accessed, downloaded, and printed by the patient. The Commission believes this could enable patients to have easier access to and use of a prescription, reduce requests for additional copies and calls from sellers to verify a prescription, and potentially lower costs while providing flexibility for prescribers and patients.

Therefore, the Commission proposes to amend § 456.1 to define the phrase "provide to the patient one copy" to mean giving a patient a copy of his or her prescription:

- (1) On paper; or

²⁷⁹ CLR Final Rule, 85 FR 50668, 50683.

(2) In a digital format that can be accessed, downloaded, and printed by the patient. For a copy provided in a digital format, the prescriber shall identify to the patient the specific method or methods of electronic delivery to be used, such as text message, electronic mail, or an online patient portal, and obtain the patient’s verifiable affirmative consent to receive a digital copy through the identified method or methods; and maintain records or evidence of a patient’s affirmative consent for a period of not less than three years. Such records or evidence shall be available for inspection by the Federal Trade Commission, its employees, and its representatives.

The full text of the proposed Rule amendment is located at the end of this document.

b. Technological Advances that May Improve Prescription Portability

Technological advances—including many spurred by federal and state health information technology initiatives²⁸⁰—have fostered the proliferation of patient portals, application programming interfaces, and other developing technologies, through which

²⁸⁰ Numerous federal and state programs have been designed to foster the development of health information technology and the electronic processing, storage, and transmission of patients’ health information. For example, under the Health Information Technology for Economic and Clinical Health Act or HITECH Act of 2009 – Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 – Congress directed the Medicare and Medicaid programs to make direct payments to eligible healthcare professionals, hospitals, and certain other healthcare providers specifically to incentivize the adoption and meaningful use of electronic health records systems (“EHRs”). American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, Division B, Title IV, §§ 4101, 4102, and 4201 (2009) (Medicare incentives for eligible professionals, Medicare incentives for hospitals, and Medicaid provider payments, respectively). According to a 2016 report, more than \$30 billion in such incentive payments were made between 2011 and 2015. U.S. Dep’t Health & Human Servs., Office of the National Coordinator for Health Information Technology, Report to Congress, “Update on the Adoption of Health Information Technology and Related Efforts to Facilitate the Electronic Use and Exchange of Health Information” 17 (2016), https://www.healthit.gov/sites/default/files/Attachment_1_-_2-26-16_RTC_Health_IT_Progress.pdf. Regarding patient portals in particular, *see, e.g.*, U.S. Dep’t Health & Human Servs., Office of the National Coordinator for Health Information Technology, “Patient Engagement Playbook,” <https://www.healthit.gov/playbook/pe/introduction/>.

health care providers can securely share medical information, such as prescription information, directly with patients. The increasing number of prescribers who have adopted various health information technologies to support patient engagement,²⁸¹ such as patient portals, has made it possible for prescribers to provide online access to prescriptions. This, along with the patient's ability to email or otherwise upload prescription copies to sellers, increases prescription portability.

Available information suggests, however, that the number of patients accessing EHRs, such as patient portals, remains limited,²⁸² and that certain patients, including older patients, are less likely to use these tools.²⁸³ Through the 21st Century Cures Act, Congress authorized HHS to take action to promote the interoperability of health IT, support the use, exchange, and access of electronic health information, and limit information blocking.²⁸⁴ The Cures Act Final Rule, promulgated by the Office of the

²⁸¹ As of 2015, 78 percent of all physicians had adopted certified health information technology. U.S. Dep't Health & Human Servs., Office of the National Coordinator for Health Information Technology, 2018 Report to Congress, "Annual Update on the Adoption of a Nationwide System for the Electronic Use and Exchange of Health Information" 8 (2018), <https://www.healthit.gov/sites/default/files/page/2018-12/2018-HITECH-report-to-congress.pdf>.

²⁸² As noted in the CLR SNPRM, a survey submitted by 1-800 CONTACTS showed that approximately 30% of patients were offered access to a portal during their last eye exam and, of those who were given the option, 29% chose to use the portal. CLR SNPRM, 84 FR 24664, 24668 n.50.

²⁸³ Heather Landi, "Who Isn't Using Patient Portals? New Study Sheds Light on Portal Use," Population Health Management (Dec. 12, 2018), <https://www.hcinnovationgroup.com/population-health-management/news/13030963/who-isnt-using-patient-portals-new-study-sheds-light-on-portal-use>. *See also* GAO, Report to Congressional Requesters, "Health Information Technology" 17 (Mar. 2017), <https://www.gao.gov/assets/690/683388.pdf> (reporting that only 15 to 30% of patients participating in the Medicare EHR program in 2015 electronically accessed their health information when it was made available to them).

²⁸⁴ 21st Century Cures Act, Pub. L. No. 114-255, Title IV (2016). "Information blocking" refers to practices that are likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. 42 U.S.C. 300jj–52.

National Coordinator for Health Information Technology (“ONC”),²⁸⁵ requires healthcare providers to enable patient access to enumerated classes of data in their electronic health record systems. These data classes include providers’ clinical notes and information on medications,²⁸⁶ and may result in consumers having greater access to their prescription information from their refractive exam.²⁸⁷

The use of patient portals for presentation of eyeglass prescriptions to sellers could provide many benefits to consumers—potentially at low marginal cost to those providers who already maintain EHRs and patient portals. When using a portal, the patient could have direct access to a current, exact copy of the eyeglass prescription, reducing the chance of errors caused by an inaccurate or expired prescription, and the need for follow-up corrections by prescribers.²⁸⁸ The use of health information technologies, such as patient portals, could also reduce costs for prescribers, patients, and sellers by making it easier and more efficient for patients to obtain and share eyeglass prescriptions and by reducing the number of requests placed on prescribers to verify prescription information, or provide duplicate copies, of prescriptions. In addition, patient

²⁸⁵ ONC, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, Final Rule, 85 FR 25642 (May 1, 2020).

²⁸⁶ See ONC, HealthIT.gov, “United States Core Data for Interoperability (USCDI),” <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>.

²⁸⁷ ONC has received proposals to include refraction measurements as a data element in the USCDI. *See* <https://www.healthit.gov/isa/uscdi-data-class/ophthalmic-data>.

²⁸⁸ Empirical studies of the integrity of electronic transmission of prescription information chiefly focus on systems for transmitting prescription drug information and not eyeglass prescriptions. Still, such studies suggest that the adoption of electronic prescribing greatly reduces the error rate associated with handwritten paper prescriptions. *See, e.g.,* Rainu Kaushal et al., “Electronic Prescribing Improves Medication Safety in Community-Based Office Practices,” 25 J. Gen. Intern. Med. 530, 530 (2010) (finding that, “For e-prescribing adopters, error rates decreased nearly sevenfold, from 42.5 per 100 prescriptions (95% confidence interval (“CI”), 36.7–49.3) at baseline to 6.6 per 100 prescriptions (95% CI, 5.1–8.3) one year after adoption ($p < 0.001$). For non-adopters, error rates remained high at 37.3 per 100 prescriptions.”).

portals may not raise the same privacy concerns expressed by some prescribers about sharing patient prescription information with third parties because patient portals can enable the secure sharing of such information directly with the patients themselves, who may then provide the prescription to the third-party seller.²⁸⁹

Accordingly, the Commission believes that the use of health information technologies, such as patient portals, to provide patients with access to electronic copies of their eyeglass prescriptions can benefit prescribers, patients, and sellers. The Commission encourages prescribers to consider whether, in addition to providing patients with copies of their prescriptions immediately following the completion of the eye examination, they should make prescriptions available electronically and online via health information technologies, in accordance with federal and state law and HHS guidance. To facilitate the likelihood that patient portals will increase prescription portability, prescribers should consider whether to configure patient portals to allow the patient to download, save, and print the prescription.²⁹⁰ In addition, prescribers should explore whether designing the portal to allow the patient to securely transmit the prescription directly to a seller will further foster prescription portability.

The proposed Rule amendment permitting electronic delivery of prescriptions to satisfy the automatic prescription release requirement expressly contemplates the use of patient portals to deliver prescriptions. Significantly, the proposed change to allow for a

²⁸⁹ See, e.g., ONC, HealthIT.gov, “Do I Need to Obtain Consent From My Patients to Implement a Patient Portal?,” <https://www.healthit.gov/faq/do-i-need-obtain-consent-my-patients-implement-patient-portal> (noting that HIPAA permits the disclosure of health information to the patient without requiring the patient’s express consent and that portals are “an excellent way to afford patients access to their own information and to encourage them to be active partners in their health care.”).

²⁹⁰ If a prescriber intends to use a patient portal to satisfy the automatic prescription release requirement of § 456.2(a), the proposed new definition of the phrase “provide to the patient one copy” would require that the prescription be provided in a digital format that can be accessed, downloaded, and printed by the patient.

digital copy in lieu of a paper copy does not alter the timing of when a prescriber must provide the prescription to the patient. In both instances, whether a digital or paper copy is given, prescribers must provide the prescription immediately after completion of the refractive eye examination. The Commission believes increased future use and adoption of health information technologies, such as patient portals, in response to the 21st Century Cures Act and other developments, have the potential to facilitate prescribers' compliance with the automatic prescription release requirement of the Rule and believe it is appropriate to provide an option for prescribers to use electronic delivery of prescriptions, so long as patients have expressly consented in advance to the mode of delivery used.

c. HIPAA Concerns Regarding Emailed Prescriptions

In response to the ANPR, the Commission did not receive any comments that identified concerns with how the Eyeglass Rule interacts with HIPAA and the HIPAA Privacy and Security Rules ("HIPAA Rules").²⁹¹ However, in other contexts, the Commission has received questions and complaints related to prescribers' HIPAA obligations under the Eyeglass Rule. For example, some prescribers have asked staff whether HIPAA precludes optometrists from emailing copies of a prescription to a patient without written authorization. Correspondingly, some consumers have complained that their eye care practitioners have cited HIPAA in refusing to email or fax eyeglass prescriptions to them.

As a preliminary matter, the HIPAA Rules do not require the prescriber to obtain a signed HIPAA authorization from a patient in order for the prescriber to release an eyeglass prescription to the patient.²⁹² The HIPAA Rules also do not prohibit covered

²⁹¹ 45 CFR parts 160, 164.

²⁹² See 45 CFR 164.502(a)(1); U.S. Dep't of Health & Human Servs., Office for Civil Rights, "Summary of the HIPAA Privacy Rule" 4-5 (2003),

prescribers from emailing eyeglass prescriptions to patients. According to guidance provided by HHS, the HIPAA Rules allow health care providers to communicate electronically with patients, provided they apply reasonable safeguards.²⁹³ Although a covered provider must consider encryption to protect against unintentional disclosures, the provider may determine that it is not reasonable and appropriate, and may instead apply ordinary precautions when transmitting unencrypted email, such as checking the email address for accuracy before sending, sending an email alert to the intended recipient for address confirmation prior to sending the message, and limiting the amount and type of protected health information (“PHI”) transmitted through the email.²⁹⁴

Moreover, where a patient requests that the covered entity transmit PHI (such as a copy of an eyeglass prescription) by unencrypted email—as is their right under the HIPAA Privacy Rule right of access—a covered entity must do so,²⁹⁵ even if the email is

<http://www.hhs.gov/sites/default/files/privacysummary.pdf> (“A covered entity is permitted . . . to use and disclose protected health information, without an individual’s authorization, for the following purposes or situations: (1) To the Individual (unless required for access or accounting of disclosures).... Covered entities may rely on professional ethics and best judgments in deciding which of these permissive uses and disclosures to make.”) (footnote omitted).

²⁹³ U.S. Dep’t Health & Human Servs., Health Information Privacy, FAQs, “Does the HIPAA Privacy Rule permit health care providers to use e-mail to discuss health issues and treatment with their patients?,” <http://www.hhs.gov/hipaa/for-professionals/faq/570/does-hipaa-permit-health-care-providers-to-use-email-to-discuss-health-issues-with-patients/>; *see also* 45 CFR 164.530(c).

²⁹⁴ Encryption of PHI must be implemented where a covered entity has determined that it is a reasonable and appropriate safeguard as part of its risk management. *See* U.S. Dep’t Health & Human Servs., Health Information Privacy, FAQs, “Is the use of encryption mandatory in the Security Rule?,” <http://www.hhs.gov/hipaa/for-professionals/faq/2001/is-the-use-of-encryption-mandatory-in-the-security-rule/index.html>. A covered health care provider also must protect PHI in those emails while they are stored on servers, workstations, mobile devices, and other computer systems, through encryption and other safeguards, as appropriate. *See* 45 CFR 164.306(a).

²⁹⁵ The HIPAA Privacy Rule right of access requires a covered prescriber to provide, upon patient request, a copy of a prescription to the patient or to another person or entity she designates. 45 CFR 164.524(c)(3); *see also* U.S. Dep’t Health & Human

an unsecure mode of transmission.²⁹⁶ Before sending unencrypted email containing PHI to a patient, the entity must advise the patient of the risk that the unencrypted PHI could be intercepted and accessed by unauthorized third parties.²⁹⁷ If, after having been advised of the risks, the patient still opts to receive his or her PHI via unencrypted email, the patient has the right to receive the PHI in that manner, and the covered entity is not liable for unauthorized access to the PHI during electronic transmission, or for safeguarding the PHI once delivered to the patient.²⁹⁸ Conversely, a covered prescriber must honor a patient's reasonable request that the prescriber *not* send communications via unencrypted email, by offering other means of delivery, such as encrypted email, secure patient portal, postal mail, or telephone.²⁹⁹

Servs., Health Information Privacy, FAQs, "Individuals' Right under HIPAA to Access their Health Information 45 CFR 164.524," <http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/>. HHS has proposed modifying the Privacy Rule to clarify that an individual's right of access to direct a provider to transmit PHI to a third party is limited to an electronic copy of PHI contained in an electronic health record. Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 FR 6446, 6462.

²⁹⁶ U.S. Dep't Health & Human Servs., Health Information Privacy, FAQs, "Do individuals have the right under HIPAA to have copies of their PHI transferred or transmitted to them in the manner they request, even if the requested mode of transfer or transmission is unsecure?," <https://www.hhs.gov/hipaa/for-professionals/faq/2060/do-individuals-have-the-right-under-hipaa-to-have/index.html> ("individuals generally have a right to receive copies of their PHI by mail or e-mail, if they request. It is expected that all covered entities have the capability to transmit PHI by mail or e-mail and transmitting PHI in such a manner does not present unacceptable security risks to the systems of covered entities, even though there may be security risks to the PHI once it has left the systems. Thus, a covered entity may not require that an individual travel to the covered entity's physical location to pick up a copy of her PHI if the individual requests the copy be mailed or e-mailed.")

²⁹⁷ Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, 78 FR 5565, 5634 (Jan. 25, 2013).

²⁹⁸ *Id.*

²⁹⁹ 45 CFR 164.522(b).

While permitting electronic delivery with a patient's verifiable consent, the proposed Rule amendment would not mandate that prescribers use electronic delivery, nor would it obligate patients to accept such delivery.³⁰⁰ As with the recent CLR amendment,³⁰¹ patients who decline to consent to electronic delivery, for any reason, must be given a paper copy of their prescription. Likewise, because technology is still developing or may be costly to implement, prescribers who prefer to provide paper copies to their patients would not be required to offer an electronic option under the amended Rule.

3. Insurance Coverage as Payment Under § 456.2(a)

The Eyeglass Rule requires that prescribers provide consumers with a copy of their prescription, but also contains an exception to allow a prescriber to refuse to give the patient a copy of their prescription until the patient has paid for the eye examination, so long as the prescriber would have required immediate payment had the eye examination revealed that no ophthalmic goods were required.³⁰² The CLR contains the same provision, but also provides that for purposes of this exception, a patient's proof of insurance coverage shall be deemed to constitute a payment.³⁰³ The Eyeglass Rule does not contain this insurance clarification, and staff has received questions from the public about this issue. The Commission believes that such a proviso, which was initially formulated by Congress in drafting the FCLCA,³⁰⁴ should be added to the Eyeglass Rule,

³⁰⁰ The proposed amendment would also not alter or pre-empt existing state and federal requirements pertaining to the electronic delivery of records and consumer consent, such as the Electronic Signatures in Global and National Commerce Act, 15 U.S.C. 7001 ("E-Sign").

³⁰¹ See CLR Final Rule, 85 FR 50668, 50682.

³⁰² 16 CFR 456.2(a).

³⁰³ 16 CFR 315.4.

³⁰⁴ 15 U.S.C. 7602.

both because it is appropriate that a patient's proof of insurance coverage equates to payment, and to bring the two rules into conformity, to eliminate unnecessary confusion. The Commission thereby proposes a technical amendment to the Rule to add a statement to the end of § 456.2(a) clarifying that the presentation of proof of insurance coverage shall be deemed to be a payment.

C. Requiring Prescribers to Respond to Authorized Third-Party Seller Requests for a Copy of Prescription or Verification of Prescription Information

In contrast to the CLR, the Eyeglass Rule does not require a prescriber to provide a copy to, or verify prescription information with, third-party sellers authorized by the patient.³⁰⁵ The Commission requested comment on whether it should amend the Rule to obligate prescribers to respond to either or both of these requests from sellers.³⁰⁶

1. Comments on Requiring Prescriber Response to Third-Party Seller Requests

Some commenters recommended that the Commission align the Eyeglass Rule with the CLR, which requires that prescribers provide authorized third parties with a copy of, and verification of, a prescription.³⁰⁷ Under the CLR, a seller may only sell contact lenses in accordance with a prescription that is presented to the seller by the patient or

³⁰⁵ The Eyeglass Rule contains the word "verification," but the meaning associated with that word is quite different from what is being considered in this discussion. Section 452.6(c) states that a prescriber may not charge a patient any fee in addition to the examination fee as a condition of releasing the prescription, but provides a caveat that the prescriber "may charge an additional fee for verifying ophthalmic goods dispensed by another seller when the additional fee is imposed at the time the verification is performed." Verification in the exception pertains to an ophthalmologist or optometrist examining the accuracy of the lenses dispensed by another seller, and not a prescriber verifying prescription information provided by a seller. *See* Eyeglass I Rule, 43 FR 23992, 23998.

³⁰⁶ *See* Eyeglass Rule ANPR, 80 FR 53274, 53276.

³⁰⁷ *See, e.g.,* NAOO (Comment #0748 submitted by Cutler); Warby Parker (Comment #0817 submitted by Kumar); Duplantier (Comment #0847); Opternative (now Visibly) (Comment #0853 submitted by Dallek).

prescriber, or verified by the prescriber.³⁰⁸ A prescription is verified only if the prescriber confirms the prescription is accurate, the prescriber informs the seller that the prescription is inaccurate and provides the accurate prescription, or the prescriber fails to respond to the seller within eight business hours after receiving a complete verification request (“passive verification”).³⁰⁹ A prescriber is also required to respond to an authorized seller’s request for a copy of a prescription.³¹⁰

The verification requirements for contact lenses derive from the FCLCA, which created the framework for contact lens sales and directed the Commission to promulgate the CLR.³¹¹ The FCLCA requires that sales of contact lenses occur only with a copy of a prescription, or after verifying a prescription with a prescriber, and sets forth the requirements for passive verification.³¹²

Commenters in favor of amending the Eyeglass Rule to require that prescribers provide copies of prescriptions to sellers, or verify prescriptions with sellers, include the NAOO, several state optician groups and individual opticians, some prescribers (including a telehealth prescriber), eyewear seller Warby Parker and some of its employees, a United States Senator, and numerous individual consumers.³¹³ Warby

³⁰⁸ 16 CFR 315.5.

³⁰⁹ *Id.*

³¹⁰ 16 CFR 315.3(a).

³¹¹ 15 U.S.C. 7607; 16 CFR 315.1.

³¹² 15 U.S.C. 7603.

³¹³ *See, e.g.*, Opticians Association of America (Comment #0638 submitted by Allen); Opticians Alliance of New York (Comment #0642 submitted by Cullen); Duff (Comment #0653); NAOO (Comment #0748 submitted by Cutler); South Carolina Association of Opticians (Comment #0822 submitted by Harbert); DeMuth Jr. (Comment #0055); Senate Majority Leader Charles Schumer (Comment #0865); Ramiah (Comment #0139); Capurso (Comment #0149); Mendelsohn (Comment #0429); Groenke (Comment #0697); Schrup (Comment #0765); Kuhl (Comment #0766); Gorsuch (Comment #0773); Frein (Comment #0774); Hopkins (Comment #0776); Feldman (Comment #0780);

Parker and a number of consumers stated that there is a need for such a requirement because, at present, when sellers request a copy or verification of prescription information, prescribers do not always respond³¹⁴ or respond in a timely fashion.³¹⁵ Warby Parker commented that it expends substantial resources “persuad[ing prescribers] to provide the information required to fill a consumer order,” and that it informs between 50 and 100 consumers per day that it is unable to complete their eyeglass orders.³¹⁶ As a result, some consumers complained that they waited a long time for their eyeglasses, or that they were ultimately unable to purchase glasses from a seller other than their

Anderson (Comment #0781); Lyden (Comment #0792); Jackson (Comment #0707); Meinke (Comment #0795); Lorenczi (Comment #0796); Keas (Comment #0798); Burkhart (Comment #0805); Albee (Comment #0806); Rivera (Comment #0809); Warby Parker (Comment #0817 submitted by Kumar); Warden (Comment #0820); Anderson (Comment #0714); Sansbury (Comment #0825); Williamson (Comment #0827); Ardis (Comment #0830); Folline Vision Centers (Comment #0837); Rump (Comment #0843); Murtha (Comment #0844); Heaton (Comment #0845); Gage-Halman (Comment #0846); Malonjao (Comment #0856). Some commenters used the term “verify” to mean that prescribers should be required to provide a copy of a prescription to an optical shop. *See, e.g.,* Debnam (Comment #0039) (consumer did not have a copy of the prescription so asked optical shop to call the doctor to verify the prescription); Panaccio (Comment #0340) (same). In other instances, it was unclear whether commenters were discussing requiring the prescriber to provide a copy of, or verify, prescriptions.

³¹⁴ *See, e.g.,* Debnam (Comment #0039); White (Comment #0053); Kidwell (Comment #0054); Averett (Comment #0057); Silva-Sadder (Comment #0065); Tresham (Comment #0737); Kulp (Comment #0150); Lass (Comment #0197); Moran (Comment #0202); Vieira (Comment #0237); Lavieri (Comment #0242); Panaccio (Comment #0340); Schermerhorn-Cousens (Comment #0350); Stout (Comment #0527); Warby Parker (Comment #0817 submitted by Kumar).

³¹⁵ *See, e.g.,* Peel (Comment #0281); Paluzzi (Comment #0412); Quinn (Comment #0427); Hollis (Comment #0430); Choi (Comment #0455); Cash (Comment #0482); Gold (Comment #0503); Poppy (Comment #0517); Schneider (Comment #0571); Crollini (Comment #0607); Pappas (Comment #0692); Peaton (Comment #0772); Benson (Comment #0777); Carter (Comment #0778); Ghaznavi (Comment #0779); Knittel (Comment #0782); Cornett (Comment #0784); Nakanishi (Comment #0789); Anderson (Comment #0797); Beeferman (Comment #0801); Taylor (Comment #0787); Todd (Comment #0802); Kelley (Comment #0804); Nguyen (Comment #0812); Necastro (Comment #0816); Warby Parker (Comment #0817 submitted by Kumar); Stauffer (Comment #0859).

³¹⁶ Comment #0817 submitted by Kumar.

prescriber.³¹⁷ Some of these commenters felt that prescribers have unfairly kept their medical information from them.³¹⁸

In addition to those comments recommending that the Commission require sellers to obtain a copy of, or verify, a prescription before manufacturing eyeglasses,³¹⁹ one commenter opined that a verification provision would promote fair competition and better options and pricing for consumers;³²⁰ and others supported rule improvements that would increase access to safe, affordable prescription eyewear.³²¹ U.S. Senator Charles Schumer commented that not having a verification requirement limits consumer choice and leads to higher prices.³²² In addition, state opticians groups, individual opticians, and

³¹⁷ Debnam (Comment #0039); White (Comment #0053); Kidwell (Comment #0054); Averett (Comment #0057); Tresham (Comment #0075); Ramiah (Comment #0139); Boyle (Comment #0605).

³¹⁸ Debnam (Comment #0039); White (Comment #0053); Kidwell (Comment #0054); Averett (Comment #0057); Silva-Sadder (Comment #0065); Tresham (Comment #0075); Kulp (Comment #0150); Lass (Comment #0197); Moran (Comment #0202); Vieira (Comment #0237); Lavieri (Comment #0242); Panaccio (Comment #0340); Schermerhorn-Cousens (Comment #0350); Stout (Comment #0527); *see also* Magida (Comment #0597) (complaining that it felt like the prescriber held prescription ransom because consumer was looking elsewhere to purchase eyeglasses).

³¹⁹ *See* note 122, *supra*.

³²⁰ Mendelsohn (Comment #0429).

³²¹ O'Dea (Comment #0188); Buntain (Comment #0531).

³²² Comment #0865. Warby Parker made similar arguments regarding consumers' need for easy access to affordable prescription glasses. Comment #0817 submitted by Kumar. According to Warby Parker, its sales model reduces the cost of eyeglasses dramatically, offering a savings of approximately 75 percent as compared to prescription eyeglasses sold in traditional retail stores. The company indicated that it sells prescription eyeglasses starting at \$95, and that consumers will often pay \$400 or more elsewhere for eyeglasses of comparable quality. *Id.* Industry statistics show that, as of late 2015, online sellers were typically 50 to 60 percent less expensive than brick and mortar locations. *See* Vision Council, "U.S. Optical Overview and Outlook," *supra* note 71, at 65 n.3.

at least one optometrist, stated that enabling sellers to verify prescriptions with a patient's optometrist or ophthalmologist would better ensure patient safety.³²³

The NAOO and Warby Parker specifically requested the Rule be amended to include "passive verification," similar to that in the CLR, which would allow the sale of eyeglasses after a seller requests prescription verification and the prescriber fails to respond within a certain period of time.³²⁴ In support, the NAOO stated that there is only a very small health or safety risk, if any, in improper fitting or inaccurate prescriptions for corrective eyewear, and such risk is substantially less for eyeglasses than contact lenses (since eyeglasses are not placed on the eye itself).³²⁵

On the other hand, several commenters, mostly prescribers, objected to amending the Rule to require prescribers to respond to sellers' requests for prescription

³²³ Opticians Association of America (Comment #0638 submitted by Allen); Opticians Alliance of New York (Comment #0642 submitted by Cullen); Duff (Comment #0653); South Carolina Association of Opticians (Comment #0822 submitted by Harbert); Groenke (Comment #0697); Schrup (Comment #0765); Kuhl (Comment #0766); Gorsuch (Comment #0773); Frein (Comment #0774); Hopkins (Comment #0776); Feldman (Comment #0780); Anderson (Comment #0781); Lyden (Comment #0792); Jackson (Comment #0707); Meinke (Comment #0795); Lorenczi (Comment #0796); Keas (Comment #0798); Burkhart (Comment #0805); Albee (Comment #0806); Rivera (Comment #0809); Warden (Comment #0820); Anderson (Comment #0821); Sansbury (Comment #0825); Williamson (Comment #0827); Ardis (Comment #0830); Folline Vision Centers (Comment #0837); Rump (Comment #0843); Murtha (Comment #0844); Heaton (Comment #0845); Gage-Halman (Comment #0846); Malonjao (Comment #0856); *see also* Jozwik (Comment #0002) (commenting that verification minimizes mistakes since the information is straight from the prescriber).

³²⁴ NAOO (Comment #0748 submitted by Cutler); Warby Parker (Comment #0817 submitted by Kumar). Mandating passive verification may make it easier and faster for those consumers who have an expired or unsigned eyeglass prescription, or who have their specifications read from their current pair. However, passive verification would not benefit consumers who do not have anything to refer to containing their eyeglass specifications.

³²⁵ Comment #0748 submitted by Cutler. The group also stated that the absence of any pattern of consumer health problems following more than ten years of the Contact Lens Rule's "passive verification" approach demonstrates that the "FTC would be justified in addressing prescriber unwillingness to verify eyeglass prescriptions by taking the same approach in the Eyeglass Rule."

information.³²⁶ The AOA did not comment on whether prescribers should be required to provide a copy of a prescription to third-party sellers,³²⁷ but “strongly oppose[d]” adding a verification process similar to that utilized under the CLR, stating that the CLR’s passive verification process had various “problems and weaknesses.”³²⁸ Another prescriber indicated that a verification requirement would waste a prescriber’s time since the customer already receives a copy of the prescription.³²⁹ The AAO recognized in its comment that the expansion of online eyeglass vendors has led to a growing need for third-party verification, but stated that ophthalmic practitioners have worked diligently to meet that need without the Eyeglass Rule mandating it.³³⁰ The AAO also contended that,

³²⁶ Publi (Comment #0040); Gupta (Comment #0446); Cerri (Comment #0509); Kiener (Comment #0593); Bolenbaker (Comment #0633); Smith (Comment #0652); Geist (Comment #0679).

³²⁷ However, as noted in Section IV.B.1 above, the Commission’s request for comment on whether prescribers should be required to provide duplicate copies upon request, the AOA responded that prescribers must be allowed to use their clinical judgment to determine whether it is appropriate to provide additional copies long after the refraction was performed. Comment #0849 submitted by Peele.

³²⁸ In its Eyeglass Rule comment, the AOA did not specify what these problems and weaknesses are. Comment #0849 submitted by Peele. However, in its comment submitted pursuant to the Contact Lens Rule review, the AOA raised concerns about, among other things, automated robocall verifications, and sellers’ lack of live contact persons available to respond to prescriber verification questions and concerns. CLR RFC Comment FTC-2015-0093-0623 submitted by Peele. In addition, the AOA has questioned the Commission’s legal authority to add a verification requirement to the Eyeglass Rule without a congressional act authorizing it to do so. Comment #0849 submitted by Peele. In this NPRM and in the Rule review more generally, the Commission analyzes whether it meets the requisite section 18 factors before recommending any changes.

³²⁹ Gupta (Comment #0446); *see also* Publi (Comment #0040) (consumer against verification requirement stating consumers already have their prescriptions).

³³⁰ Comment #0864 submitted by Haber. The AAO stated that if practitioners are inflexible with regard to providing duplicate copies or verifying prescriptions, patients will go elsewhere for their eye care needs. *See also* NAOO (Comment #0748 submitted by Cutler) (stating most of its members honor requests to verify eyeglass prescriptions at no charge, but recognizing most members do not dispense eyeglasses, and therefore, have less monetary incentive to ignore or decline such requests).

due to the larger volume of eyeglass prescriptions as compared to contact lens prescriptions, amending the Rule to require strict timeframes for prescribers to respond to verification requests would pose undue financial burden on prescribers.³³¹

2. Analysis of Whether to Amend the Rule to Require Prescriber Response

The Commission declines to propose to amend the Rule to require that prescribers respond to third-party requests for prescriptions or the verification of prescription information. The Commission bases this decision on a number of factors. Initially, the Commission notes that the evidence regarding this issue is primarily anecdotal and the Commission does not, at present, have adequate data as to the number of such third-party requests, nor the percentage of requests that prescribers decline to fulfill. Furthermore, according to comments from the AAO and the AOA, many prescribers are complying with patient requests for duplicate copies of their prescription, even without such conduct being mandated by the Eyeglass Rule.³³² This may be because prescribers are required to

³³¹ Comment #0864 submitted by Haber. There are approximately 165 million eyeglass wearers compared to about 45 million contact lens wearers. *See* VisionWatch Report, *supra* note 70, at 24 (165.4 million eyeglass wearers; 42.4 million contact lens wearers); Centers for Disease Control and Prevention, Contact Lenses: Fast Facts (July 26, 2018), <https://www.cdc.gov/contactlenses/fast-facts.html> (an estimated 45 million contact lens wearers in the U.S.). Although more individuals in the United States wear eyeglasses than contact lenses, many consumers do not order a new pair of eyeglasses every year. In fact, in 2019, consumers purchased approximately 79 million pairs of eyeglass frames and 88 million pairs of lenses, whereas nearly 103 million contact lens units were sold in the same period. *See* VisionWatch Report, *supra* note 70, at 12, 82. Further, many contact lens wearers make more than one order in a year. “The Strength of Competition in the Sale of Rx Contact Lenses: An FTC Study,” 45-46 n.18 (2005), <https://www.ftc.gov/sites/default/files/documents/reports/strength-competition-sale-rx-contact-lenses-ftc-study/050214contactlensrpt.pdf> (finding that just 12-20 percent of consumers purchase a year’s supply at a time). As a result, the burden of responding to requests for a copy of, or verification of, eyeglass prescriptions is not necessarily greater than that for contact lens prescriptions.

³³² AAO (Comment #0864 submitted by Haber) (duplicate copies traditionally provided at no charge); AOA (Comment #0849 submitted by Peele) (calling provision of duplicate copies common practice among optometrists); Haas (Comment #0359); Sharma (Comment #0609); Berry (Comment #0673).

respond to patient requests for their prescription under HIPAA's right of access to medical records and many state laws.³³³

Moreover, the Commission has proposed a requirement for prescribers to obtain a signed confirmation from patients that they received a copy of their prescription. It is the Commission's belief that this proposal will remind prescribers to release prescriptions and increase compliance with the automatic release provision of the Rule,³³⁴ resulting in more patients in possession of their prescription, and, consequently, less need for third-party verification. The signed confirmation proposal, in conjunction with consumers' ability to access an additional copy of their prescription through HIPAA, other laws, or voluntary release by prescribers, should ensure that the vast majority of consumers have a prescription in hand. With that prescription, consumers should experience greater convenience and flexibility, including increased choice of style and service, and lower costs.

The Commission's goal in adopting the Confirmation of Prescription Release requirement is to further the purpose of the Rule: to enable consumers to comparison-shop for eyeglasses. The Commission is mindful that, at present, a significant percentage of prescribers do not automatically provide a prescription, and many consumers cannot reasonably avoid the resulting injury.³³⁵ The Commission is hopeful that compliance will improve without adding a requirement that prescribers provide prescriptions to, or verify

³³³ 45 CFR 164.524(c). Although in order to exercise this right, consumers may have to file a formal HIPAA request and wait several days. *See* note 252, *supra*. Consumers in most states have a separate right of access to their medical records, including prescriptions, under state law. *See* Health Information and the Law, Individual Access to Medical Records: 50 State Comparison, <http://www.healthinfolaw.org/comparative-analysis/individual-access-medical-records-50-state-comparison> (compiling and explaining state laws that give consumers the right to access their medical records).

³³⁴ *See* Section IV.A.6, *supra*.

³³⁵ *See* Section IV.A.4, *supra*.

prescriptions with, third parties.³³⁶ The Commission therefore believes it is unnecessary at this time to impose possible additional costs upon prescribers that might arise from mandating they respond directly to third-party sellers' requests,³³⁷ but may revisit this issue in the future if we receive additional information.

V. Prescription Requirements

A. Requiring Prescribers to Include Pupillary Distance on Eyeglass Prescriptions

The Commission's ANPR sought feedback on whether the Commission should amend the Rule's definition of prescription to require that prescribers provide pupillary distance on a prescription.³³⁸ Pupillary distance is the measurement (in millimeters) of the distance between the pupils of one's eyes and is a measurement needed to properly fit a pair of eyeglasses.³³⁹ Unlike a patient's refraction dimensions (sphere, cylinder, etc.), pupillary distance remains relatively constant for adults over time, although it can change

³³⁶ The Commission is not indicating that prescribers should ignore such requests, but rather is declining to propose to amend the Rule to mandate such a response.

³³⁷ Several commenters pointed out that there is a burden associated with requiring prescribers to respond to requests for a copy of, or to verify a third-party seller's request for, a prescription, though they do not agree on how large the burden is. NAOO (Comment #0748 submitted by Cutler) (declaring that the overall burden would be trivial when compared to the benefits); Kiener (Comment #0593) (processing third-party requests poses a not insignificant operating expense); Opternative (now Visibly) (Comment #0853 submitted by Dallek) (stating its willingness to take on the burden for the benefit of greater consumer choice). Although the AOA did not address the burden of verification in its comment to the Eyeglass Rule, its comments during the CLR review raised concerns about the burden presented from the CLR's verification requirement. CLR RFC Comment FTC-2015-0093-0623 submitted by Peele.

³³⁸ Eyeglass Rule ANPR, 80 FR 53274, 53276.

³³⁹ See ACLens "Measuring Pupillary Distance (PD)," <https://www.aclens.com/measuring-pupillary-distance>. As discussed later in this section, some commenters explained that a pupillary distance measurement is more complex than this definition suggests.

a small amount.³⁴⁰ According to prescriber and optician comments, providing a consumer with an accurate pupillary distance is important to the health of the patient,³⁴¹ as wearing eyeglasses made based on an inaccurate measurement can lead to visual discomfort,³⁴² headaches,³⁴³ or even vision loss for some children.³⁴⁴

Under the Rule, a prescription is defined as “the written specifications for lenses for eyeglasses which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses.”³⁴⁵ The Rule defines an eye examination as “the process of determining the refractive condition of a person’s eyes or the presence of any visual anomaly by the use of objective or subjective tests.”³⁴⁶ The purpose of the Rule’s “prescription” definition is to effectuate

³⁴⁰ NAOO (Comment #0748 submitted by Cutler); *see also* Barry Santini, “The Power and Politics of the PD,” 20/20 Magazine (Mar. 2014), <http://www.2020mag.com/1-and-t/46893/> [hereinafter Santini article] (explaining that the average change in pupillary distance is three percent between the ages of 18 and 50, and changes even more slowly after the age of 60).

³⁴¹ *See, e.g.*, Opticians Association of America (Comment #0638 submitted by Allen); Opticians Association of Kentucky (Comment #0640 submitted by Castle); Opticians Association of Vermont (Comment #0641 submitted by Williams); Opticians Alliance of New York (Comment #0642 submitted by Cullen); South Carolina Association of Opticians (Comment #0822 submitted by Harbert); Robinson (Comment #0643); Duff (Comment #0653); Johnson (Comment #0654); Thetford (Comment #0659); Crabtree (Comment #0666); Groenke (Comment #0697).

³⁴² Several commenters also pointed out that an accurate pupillary distance is even more important for those consumers who have higher-powered prescriptions. *See, e.g.*, Opticians Association of Alaska, Inc. (Comment #0852 submitted by Brand); Heuer (Comment #0670); LensCrafters (Comment #0819 submitted by Tavel).

³⁴³ Clark (Comment #0855).

³⁴⁴ Opticians Association of Alaska, Inc. (Comment #0852 submitted by Brand) (incorrect pupillary distance for child with amblyopia (commonly known as “lazy eye”) could lead to further vision loss and impairment); Peaslee (Comment #0700) (an incorrect pupillary distance could permanently damage a child’s vision).

³⁴⁵ 16 CFR 456.1(g).

³⁴⁶ 16 CFR 456.1(b).

the separation of the exam and the sale of eyeglasses; it is not intended to preempt state regulations that determine what must be included in a prescription.³⁴⁷ A review of current state laws demonstrates that only four states require the inclusion of pupillary distance in a prescription.³⁴⁸

Prior to the Rule's initial issuance, the Commission considered whether to require that prescriptions contain pupillary distance. After considering the various comments concerning whether pupillary distance and other measurements needed to make eyeglasses were part of the eye examination or the dispensing of eyeglasses, and whether prescribers or opticians were more qualified to take pupillary distance measurements, it left to the states the determination of whether a pupillary distance measurement was required prescription information.³⁴⁹

The manner of purchasing eyeglasses when the Commission first promulgated the Rule differed greatly from the present, however. Then, if a prescriber did not provide pupillary distance on prescriptions, consumers could generally obtain that measurement at the brick and mortar business where they purchased their eyeglasses. Today, consumers also have the option to purchase their eyeglasses online and need that measurement to place their order. Several commenters to this Rule review suggested that the Rule should now be amended to require that prescriptions include a patient's pupillary distance.³⁵⁰

³⁴⁷ See 16 CFR 456.1(g).

³⁴⁸ Alaska Admin. Code tit. 12, § 48.920; Kan. Admin. Regs. § 65-8-4; 246 Mass. Code Regs. § 3.02; N.M. Stat. Ann. § 61-2-10.3. Arizona once required pupillary distance on prescriptions, but that requirement was removed. Ariz. Admin. Code § R4-21-306 (amended by final rulemaking at 22 Ariz. Admin. Reg. 328, eff. Mar. 28, 2016).

³⁴⁹ Eyeglass I Report, *supra* note 6, at 255-59.

³⁵⁰ See note 357, *infra*.

Understanding what currently occurs in the marketplace with respect to pupillary distance informs the Commission’s discussion and analysis. Some prescribers who measure pupillary distance provide it on prescriptions automatically; others provide it free upon request or for a nominal fee, while others refuse to provide it to consumers.³⁵¹ Other prescribers do not ordinarily take pupillary distance, leaving that task to the optical dispensary that crafts a patient’s eyeglasses. Some prescribers, particularly some ophthalmologists, commented that they do not have equipment to measure pupillary distance.³⁵²

Consumers who do not receive their pupillary distance on their prescription, and desire to purchase their eyeglasses online, are able to obtain that measurement in other ways, though it may cost them time, money, or, according to some commenters, accuracy. If the information is in a patient’s medical file, the individual may obtain it by filing a HIPAA request, a process that may require filling out a form, paying a fee, and waiting up to 30 days.³⁵³ Consumers may also obtain their pupillary distance

³⁵¹ NAOO (Comment #0748 submitted by Cutler); *see also* Fainzilberg (Comment #0051) (prescriber did not initially provide pupillary distance and later refused to give the measurement out over the phone); Wintermute (Comment #0067) (prescriber refused to provide pupillary distance measurement); Riding (Comment #0100) (prescriber gave consumer the “runaround” and provided the pupillary distance measurement a couple weeks after the request); Morris (Comment #0104) (prescriber did not provide the pupillary measurement on the prescription); Bray (Comment #0105) (same); Parazette-Nascimbene (Comment #0106) (same); Twardowski (Comment #0110) (same). The FTC has received complaints from consumers stating that their prescription did not include, or that their prescriber refused to provide them with, their pupillary distance. Other consumer complaints received by the FTC indicate that consumers have been charged by prescribers between \$15 and \$40 for a pupillary distance measurement.

³⁵² *See, e.g.*, Narula (Comment #0578); Hoffman (Comment #0587); Groenke (Comment #0697) (requirement would possibly mean prescribers would need to purchase expensive equipment); Hopkins (Comment #0776) (same); LensCrafters (Comment #0819 submitted by Tavel) (stating that the digital technology required to accurately obtain these measurements does not typically exist in the doctor’s space); Alvarez (Comment #0838).

³⁵³ 45 CFR parts 160, 164 (HHS has proposed reducing this time to require access be provided “as soon as practicable,” but in no case later than 15 days. *See* note 252,

measurements by visiting a third-party brick and mortar store. Consumers may have to pay for this measurement, although at least one online seller has offered to reimburse consumers up to a certain dollar amount for the measurement. Online sellers also offer directions and online tools for consumers to measure their own pupillary distance, or to have someone they know measure their pupillary distance.³⁵⁴ Techniques suggested vary from using a credit card and webcam to using a millimeter ruler and a mirror.³⁵⁵ However, some consumers reported problems with their vision when using eyeglasses made with pupillary distances they measured themselves using online tools.³⁵⁶ It should be also pointed out that commenters did not opine on, and the Commission has not analyzed, whether the various methods consumers may use to determine their pupillary distance, or whether sellers manufacturing eyeglasses in accordance with self-measured pupillary distances, are permitted in all jurisdictions.

3. Comments on Whether to Require Pupillary Distance

Comments in favor of requiring that prescriptions contain pupillary distance were primarily from consumers, Warby Parker, and Warby Parker employees.³⁵⁷ These

supra). One complication with filing a HIPAA request, however, is that a consumer may not know whether a pupillary distance measurement is in their doctor's medical file, and might not be able to find out until receiving the records. Some consumers, though, may already possess a previous prescription containing their pupillary distance.

³⁵⁴ See, e.g., Zenni Optical, "How to Measure Your Pupillary Distance (PD)," <http://www.zennioptical.com/measuring-pd-infographic>; Warby Parker, "Measure your pupillary distance (PD)," <https://www.warbyparker.com/pd/instructions>. .

³⁵⁵ *Id.*

³⁵⁶ See note 362, *infra*.

³⁵⁷ See, e.g., Fainzilberg (Comment #0051); Wintermute (Comment #0067); Dingley (Comment #0062); DeLisle (Comment #0070); Twardowski (Comment #0110); Ramiah (Comment #0139); Cooney (Comment #0159); Dickens (Comment #0176); O'Dea (Comment #0188); Bailer (Comment #0191); Wiczorkowski (Comment #0210); Mackey (Comment #0739); Washington (Comment #0320); Beaudoin (Comment #0349); Myers (Comment #0351); Montgomery (Comment #0375); Greco (Comment #0406); Warby Parker (Comment #0817 submitted by Kumar); Cornwell (Comment

commenters declared that the Rule should include pupillary distance to increase prescription portability and, therefore, the procompetitive effects of the Rule.³⁵⁸ Warby Parker and consumers recounted numerous instances where they felt prescribers had engaged in anti-competitive behavior by refusing to provide, or by charging for, the measurement.³⁵⁹ Warby Parker also alleged that prescribers refuse to give this measurement as a tactic to keep business because they know that consumers who request this measurement are taking their eyeglass business online.³⁶⁰ Some consumers stated that they had to obtain their pupillary distance from another brick and mortar store before buying online, making it far less convenient to obtain new eyeglasses.³⁶¹ Some consumers said that they measured their pupillary distance themselves, but as a result experienced problems with their glasses.³⁶² The NAOO commented that self-estimating pupillary distance can result in lower accuracy and a higher number of eyeglass remakes, but that many online sellers have developed accurate alternative ways to measure pupillary distance.³⁶³

#0829). *But see* Santini (Comment #0047) (optician in favor of adding a pupillary distance requirement to the Rule); 1-800 CONTACTS (Comment #0834 submitted by Williams) (in favor of adding a pupillary distance requirement to the Rule).

³⁵⁸ *Id.*

³⁵⁹ *See, e.g.,* Warby Parker (Comment #0817 submitted by Kumar); Fainzilberg (Comment #0051); Wintermute (Comment #0061); Wieczorkowski (Comment #0210); Mackey (Comment #0739); Montgomery (Comment #0375); Savransky (Comment #0378).

³⁶⁰ Warby Parker (Comment #0817 submitted by Kumar).

³⁶¹ *See, e.g.,* Kao (Comment #0107); Evans (Comment #0109); Martin (Comment #0103); Nitekman (Comment #0112); Huet (Comment #0114); Cayabyab (Comment #0115); Smith (Comment #0118); Webb (Comment #0121); Grazado (Comment #0122); Weinberger (Comment #0123); Skinner (Comment #0124).

³⁶² Bailer (Comment #0191); Emanuel (Comment #0282); Land (Comment #0311).

³⁶³ Comment #0748 submitted by Cutler.

Warby Parker also commented that the Commission has previously objected to state regulatory proposals designed to withhold certain information necessary to fill an eyeglass prescription.³⁶⁴ The eyeglass seller pointed to a 2011 FTC staff letter responding to the North Carolina State Board of Opticians' proposed rule that would have, among other things, redefined the meaning of prescriptions for eyeglasses and contact lenses so that "measurements taken by opticians are not considered part of the patient's prescription, and are not required to be released as part of a prescription."³⁶⁵ The 2011 staff letter, which did not specifically mention pupillary distance, was not an opinion by staff that pupillary distance is a necessary part of a valid eyeglass prescription, or that failure to include pupillary distance is an unfair act or practice. Rather, Commission staff was concerned that adoption of the North Carolina proposal would decrease consumers' existing access to information.³⁶⁶ By contrast, the current document considers whether to designate a failure to include pupillary distance as an unfair act or practice.

In contrast to Warby Parker and consumer commenters, ophthalmologists and optometrists commenting on the Rule almost universally declared that the Rule should not require that a prescription contain pupillary distance.³⁶⁷ Some prescribers, especially ophthalmologists, stated that they do not take this measurement.³⁶⁸ The AOA and

³⁶⁴ Comment #0817 submitted by Kumar.

³⁶⁵ Letter from Susan S. DeSanti, Director, Office of Policy Planning, Joseph Farrell, Director, Bureau of Economics, and Richard A. Feinstein, Director, Bureau of Competition to Sue M. Kornegay, NC State Board of Opticians, Jan. 13, 2011, https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-north-carolina-state-board-opticians-concerning-proposed-regulations-optical-goods/1101ncopticiansletter.pdf.

³⁶⁶ *Id.*

³⁶⁷ The AOA commented that the Rule should continue to defer to the states on this issue. Comment #0849 submitted by Peele.

³⁶⁸ Pandit (Comment #0449) (ophthalmologist); Nichols (Comment #0461) (ophthalmologist); Perlmutter (Comment #0464) (ophthalmologist); Chung (Comment

LensCrafters commented that prescribers do not routinely take this measurement as part of an “eye examination.”³⁶⁹ Other prescribers indicated that while they take a “binocular” pupillary distance measurement during their examination, this is not always precise enough for an optician to use in making eyeglasses.³⁷⁰

Prescribers further indicated that their principal opposition to a requirement that they include a pupillary distance on a prescription is that the measurement is part of the dispensing of eyeglasses and not part of a refractive examination,³⁷¹ and that the costs

#0474) (ophthalmologist); Holler (Comment #0615) (ophthalmologist who has never taken pupillary distance in 17 years); Rosenblum (Comment #0629) (ophthalmologist who has never taken a pupillary distance); Alvarez (Comment #0838) (optometrist who has never taken a pupillary distance).

³⁶⁹ AOA (Comment #0849 submitted by Peele); LensCrafters (Comment #0819 submitted by Tavel). It follows, according to the AOA, that since pupillary distance is not derived as part of an “eye examination,” it does not meet the Rule’s definition of a prescription, and should not be required. Comment #0849 submitted by Peele.

³⁷⁰ Robinson (Comment #0625); *see also* Shepard (Comment #0476) (forcing eye doctors to use old technology to write the pupillary distance on a prescription would be legislating old and outdated technology and not in the interest of patients); Hixson (Comment #0810) (the pupillary distance taken during the exam is an estimate and is often highly inaccurate). Eyeglass manufacturer and seller, ACLens, describes on its website that a binocular measurement is a measurement from one eye’s pupil to the other. Monocular PD consists of two numbers and is the distance between the centers of each pupil to the bridge of the nose. <https://www.zennioptical.com/measuring-pd-infographic>. Some commenters stated that a monocular pupillary distance provides better centration and is therefore preferable for use in manufacturing eyeglasses. *See* LensCrafters (Comment #0819 submitted by Tavel).

³⁷¹ *See, e.g.,* AAO (Comment #0864 submitted by Haber); AOA (Comment #0849 submitted by Peele); Johnson (Comment #0654); Lowe (Comment #0380); Nichols (Comment #0461); Shepherd (Comment #0476); Patterson (Comment #0469); Chung (Comment #0474); Wareham (Comment #0498); Yuhas (Comment #0505); Mangano (Comment #0525); Groenke (Comment #0697); Hopkins (Comment #0776); Alvarez (Comment #0838). This view represents a change from the position many prescribers used to hold about what ought to be included in a prescription. Prior to adoption of the Eyeglass Rule, many in the optometric industry strenuously advocated for “total vision care,” in which it was the prescriber’s responsibility to determine all of the parameters required to fabricate a pair of eyeglasses, including pupillary distance. *See* Eyeglass I Report, *supra* note 6, at 255-57 (citing testimony from the Indiana Optometric Association, Ohio State University College of Optometry, and Ron Fair, former president of the AOA).

associated with taking these measurements are built into the eyewear product and not the examination.³⁷² Some prescribers stated that if taking a pupillary distance were to become a required part of an eye examination, the price of an eye examination would increase.³⁷³ In fact, a number of prescribers commented that if required to include it, they would have to acquire new equipment and hire or train staff to take this measurement.³⁷⁴ The AAO suggested that the addition of such a requirement might cause ophthalmologists to stop providing vision-correction exams for eyeglasses and contacts altogether, and focus solely on eye health and medical issues.³⁷⁵

Opticians, in general, are also largely opposed to the Rule requiring that a prescription contain pupillary distance.³⁷⁶ Many opticians suggested that the pupillary

³⁷² *See, e.g.*, Jones (Comment #0584); Goldberg (Comment #0824); AAO (Comment #0864 submitted by Haber).

³⁷³ Patterson (Comment #0469); Groenke (Comment #0697); Hopkins (Comment #0776); AAO (Comment #0864 submitted by Haber). As a way to offset these costs, some commenters recommend that prescribers be able to charge consumers for this measurement. Kirkham (Comment #0511); Goodhew (Comment #0731).

³⁷⁴ *See, e.g.*, Rosenblum (Comment #0629) (cost of providing care to patients will increase if he must hire an optician or optometrist); Hopkins (Comment #0776) (new equipment); Goldberg (Comment #0824) (prescribers are not trained and do not have staff to take pupillary distance); AAO (Comment #0864 submitted by Haber) (would have to hire extra staff); Narula (Comment #0578) (would require acquisition of costly equipment).

³⁷⁵ AAO (Comment #0864 submitted by Haber); *see also* Kim (Comment #0508); Croyle (Comment #0519).

³⁷⁶ *See, e.g.*, Opticians Association of America (Comment #0638 submitted by Allen); Opticians Alliance of New York (Comment #0642 submitted by Cullen); Opticians Association of Iowa (Comment #0646 submitted by Dalton); Opticians Association of Virginia (Comment #0647 submitted by Nelms); Poe (Comment #0648); Montavon (Comment #0649); Professional Opticians of Florida (Comment #0803 submitted by Couch); Opticians Association of Alaska, Inc. (Comment #0852 submitted by Brand); Shelton (Comment #0585); Evans (Comment #0661); Damisch (Comment #0675); Whatley (Comment #0676); Jackson (Comment #0793); Wood (Comment #0709); Chamberlain (Comment #0713); Connor (Comment #0721); Tanzi (Comment #0723); Oxenford (Comment #0724); Reed (Comment #0738); Shroyer (Comment #0743); Ahrens (Comment #0022); Hummel (Comment #0788). While the NAOO was unable to reach a consensus on this issue, it recognized that the absence of a pupillary

distance measured by a prescriber's office should not be used to make eyeglasses.³⁷⁷

Some opticians agreed with the prescribers who commented that prescribers' equipment is not always sufficiently precise.³⁷⁸ Opticians stated that an accurate measurement depends on the intended use of the eyeglasses (*e.g.*, reading, computer use, driving) and specific frames chosen,³⁷⁹ the latter being information that a prescriber rarely has at the time the prescription is written following the exam. According to some commenters, to obtain an accurate pupillary distance, one needs to know specifically the lens shape and size, as well as the horizontal and vertical placement of the glasses on an individual's face.³⁸⁰ Some commenters also noted that there may be different pupillary distance

distance on a prescription creates hurdles for consumers who wish to purchase their eyeglasses online. Comment #0748 submitted by Cutler.

³⁷⁷ See, *e.g.*, Opticians Association of America (Comment #0638 submitted by Allen); Shelton (Comment #0585); Opticians Association of Iowa (Comment #0646 submitted by Dalton); Parent (Comment #0693); Evans (Comment #0661); Damisch (Comment #0675); Whatley (Comment #0676); Reynolds (Comment #0726).

³⁷⁸ Opticians Association of Alaska, Inc. (Comment #0852 submitted by Brand); Fitzgerald (Comment #0818); *see also* Cooper (Comment #0562) (ophthalmologist who indicates he would be unable to provide an accurate pupillary distance measurement to his patients); LensCrafters (Comment #0819 submitted by Tavel) (stating that the digital technology required to accurately obtain the pupillary distance does not typically exist in the doctor's space).

³⁷⁹ Edwards (Comment #0360); Cervantes (Comment #0671); Ahrens (Comment #0022); Stuart (Comment #0841); *see also* Shepherd (Comment #0476) (prescriber); Archibald (Comment #0729) (optometrist).

³⁸⁰ Opticians Association of Virginia (Comment #0647 submitted by Nelms); Cervantes (Comment #0671); Archibald (Comment #0729); Ahrens (Comment #0022); *see also* Santini article, *supra* note 340 (as the sophistication of eyeglass lenses has advanced, prescribers have improved their understanding of how measurements beyond simple pupil location help optimize lens acuity, comfort, and utility). Commenters also stated that other measurements are needed for dispensing eyeglasses, such as base curve and segment height, and that prescribers are not also required to take those measurements. Edwards (Comment #0360) (as important as the pupillary distance generally is, other measurements and considerations are at least as important); Kalish (Comment #0048); Haas (Comment #0359); Yuhass (Comment #0505); Rosenblum (Comment #0629).

measurements for near and far viewing distances, and so multi-focal lenses may have more than one pupillary distance.³⁸¹

Opticians indicated they are trained to take an accurate pupillary distance as part of the process of fitting eyeglasses, whereas prescribers are not specifically trained to take this measurement.³⁸² According to these opticians, if prescribers are required to provide pupillary distance on a prescription, some opticians will by law be forced to adhere to the measurement on the prescription, rather than to their own measurement, which might be more accurate.³⁸³ For instance, in North Carolina, state law specifies that an optician may not contradict measurements taken by a prescriber; in Oregon, opticians are required to grind eyeglasses in conformity with prescriptions.³⁸⁴ Should the Commission require prescribers to include pupillary distance on prescriptions, opticians in North Carolina, Oregon, and other states with similar laws might no longer have the right to make glasses from their own pupillary distance measurements. Opticians also

³⁸¹ Narula (Comment #0578); Hamilton (Comment #0867); Hamilton (Comment #0868); Archibald (Comment #0729); LensCrafters (Comment #0819 submitted by Tavel); *see also* ACLens, “Measuring Pupillary Distance (PD),” <https://www.aclens.com/measuring-pupillary-distance> (stating that if a consumer requires prescription bifocal glasses she will need both a near and distance PD and that the near PD is calculated by subtracting 3mm from the distance PD).

³⁸² *See, e.g.*, Opticians Association of America (Comment #0638 submitted by Allen); Damisch (Comment #0675). Some prescribers corroborated optician comments as to opticians’ ability or training to take these measurements, or as to their own lack of training or ability to take these measurements. Lunsford (Comment #0346); Wnorowski (Comment #0484); Kopp (Comment #0491); Cooper (Comment #0562); Narula (Comment #0578); Fyffe (Comment #0581); Rosenblum (Comment #0629).

³⁸³ *See, e.g.*, Opticians Association of America (Comment #0638 submitted by Allen); Opticians Association of Kentucky (Comment #0640 submitted by Castle); Opticians Association of Vermont (Comment #0641 submitted by Williams); Opticians Alliance of New York (Comment #0642 submitted by Cullen); Robinson (Comment #0643); Duff (Comment #0653); Johnson (Comment #0654); Thetford (Comment #0659); Crabtree (Comment #0666); Groenke (Comment #0697); Hopkins (Comment #0776); South Carolina Association of Opticians (Comment #0822 submitted by Harbert).

³⁸⁴ 21 N.C. Admin. Code 40.0210; Or. Rev. Stat. § 683.520.

expressed concern that this might make them liable for errors resulting from improper measurements written by a prescriber and that they would have to absorb the costs involved in remaking the glasses, or pass along those costs to consumers.³⁸⁵

4. Analysis of Whether to Amend the Rule to Require Pupillary Distance

To determine that an act or practice is unfair, the Commission must find that the act or practice causes or is likely to cause substantial injury to consumers; the injury is not reasonably avoidable by consumers themselves; and, the injury is not outweighed by countervailing benefits to consumers or to competition.³⁸⁶ As previously discussed, purchasing eyeglasses online can be more convenient and less costly for consumers.³⁸⁷ Without a pupillary distance measurement included on their prescriptions, some consumers may be hampered in their ability to shop online for eyeglasses because they must obtain this information independently. However, since other methods are available for consumers to obtain this measurement and use it to comparison shop, the Commission does not believe, at this time, that there is an adequate record to demonstrate that prescribers' failure to provide pupillary distance measurements on prescriptions constitutes substantial injury. As discussed above, those consumers who wish to shop online and do not already have their pupillary distance can obtain that measurement

³⁸⁵ *See, e.g.*, Opticians Association of America (Comment #0638 submitted by Allen); Opticians Association of Vermont (Comment #0641 submitted by Williams); Opticians Alliance of New York (Comment #0642 submitted by Cullen); Opticians Association of Kentucky (Comment #0640 submitted by Castle); Robinson (Comment #0643); Duff (Comment #0653); Johnson (Comment #0654); Thetford (Comment #0659); Crabtree (Comment #0666); Groenke (Comment #0697); Hopkins (Comment #0776); South Carolina Association of Opticians (Comment #0822 submitted by Harbert). On the other hand, some prescribers expressed concerns that they would be liable for mistakes made by opticians who use prescribers' pupillary distance measurements. Chung (Comment #0454); Nichols (Comment #0461); Michel (Comment #0472); Azar (Comment #0518).

³⁸⁶ 15 U.S.C. 45(n).

³⁸⁷ *See* Section I.C, *supra*.

through other methods, many of which are no cost or relatively low-cost, and can thereafter provide sellers with this information. For example, a number of online sellers offer directions and online tools for consumers to measure their own pupillary distance, or to have someone they know measure their pupillary distance, using readily available objects like a credit card and a webcam.³⁸⁸

In addition, according to many prescribers and optician commenters, imposing a requirement to include pupillary distance in the prescription may be detrimental for prescribers and consumers in one or more of the following ways. Some prescribers would be required to take a measurement that they do not ordinarily take, or have never taken. According to commenters, due to a prescriber's use of inadequate equipment, or a lack of training, and the fact that prescribers do not have the benefit of adjusting the pupillary distance to accommodate the fit of a particular pair of eyeglasses, consumers may obtain inaccurate measurements.³⁸⁹ Moreover, it is possible that optician reliance on a prescriber's measurements, mandated by law in some jurisdictions, could result in improperly-made eyeglasses, which would increase the inconvenience and cost to opticians, consumers, and prescribers.³⁹⁰ If an optician makes a pair of eyeglasses using a prescriber-provided pupillary distance measurement that a consumer finds uncomfortable, the consumer would need to obtain a new prescription containing a revised pupillary distance before an optician could remake the eyeglasses. If these prescribers and optician commenters are correct, a requirement to include pupillary distance in prescriptions could be detrimental to consumers and competition.

³⁸⁸ See Section V.A, *supra*.

³⁸⁹ See notes 378-382, *supra*.

³⁹⁰ See notes 383, 385, *supra*.

In addition, if the Commission required prescribers to include pupillary distance measurements on prescriptions, it is unlikely that prescribers would use less expensive pupillary distance rulers and the like, but instead—for professional and liability reasons—would likely select more technologically sophisticated methods, such as a digital centration device, to take the measurement. Such devices, and the training, staff, and exam time necessary to operate the devices, could be costly. Some prescribers could pass these costs on to their patients in the form of higher prices.³⁹¹ Alternatively, some prescribers could choose not to provide refractive services.³⁹²

As is evidenced by the title of the Rule, “Separation of examination and dispensing,” the Rule distinguishes between the examination that determines refraction and the sale of eyeglasses. Pupillary distance involves the fitting of a pair of eyeglasses to one’s face, and is thus typically considered part of the dispensing process. If the Commission required prescribers to include pupillary distance on prescriptions, in offices with dispensaries, the prescriber, instead of adding expensive pupillary-distance measurement equipment to the exam room, might lead the patient into the dispensary to measure the patient’s pupillary distance. Such a shift would place the patient in the dispensary prior to the patient receiving her prescription, undercutting both the Rule’s requirement to release eyeglass prescriptions to patients immediately upon completion of an eye examination, and the Rule’s long-standing emphasis on keeping the refractive examination distinct from, and untied to, the sale of eyeglasses.

Based on its consideration of the relevant factors, the Commission is not convinced that there is adequate evidence in the current rulemaking record to determine

³⁹¹ See note 373, 374, *supra*.

³⁹² See note 375, *supra*.

that the failure to provide a pupillary distance on a prescription is an unfair practice.³⁹³

The Commission therefore does not propose requiring prescribers to include the pupillary distance measurement on prescriptions. It does not appear to the Commission that the potential benefits to consumers or competition from a Rule change requiring the inclusion of pupillary distance on prescriptions outweigh the consequences detailed by prescribers and opticians, especially if consumers who wish to purchase their eyeglasses online can obtain their pupillary distance independently, at no cost or a relatively low cost. The Commission understands that requiring prescribers to provide pupillary distance might be more convenient for some consumers and online retailers, and may help foster a competitive market, but the Commission believes, as it did at the time of the Rule's issuance, that absent a record demonstrating that the failure to include pupillary distance as part of the prescription constitutes an unfair practice, the states should continue to determine the contents of eyeglass prescriptions.³⁹⁴ The Commission recognizes that it last invited comment on the question of whether to require the inclusion of pupillary distance in a prescription in its 2015 ANPR,³⁹⁵ and the online market for optometry and

³⁹³ Since the Commission has not found the practice of failing to include a pupillary distance measurement on a prescription to be unfair, it does not need to evaluate whether this practice is prevalent.

³⁹⁴ See Section V.A, *supra* (explaining that the Rule's definition of prescription, as the "written specifications for lenses for eyeglasses which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses," 16 C.F.R. § 456.1, leaves it to the states to determine what must be included in a prescription, and that only four states currently require the inclusion of pupillary distance measurements on prescriptions); *see also*, Section I.D, *supra* (discussing how state laws and regulations, and not the Eyeglass Rule, govern most aspects of professional practice and eyewear sales). Some commenters recommended that the Commission require a prescription to include a "best corrected visual acuity" or "best corrected vision," a measurement that allows the person filling the eyeglass prescription to know what line of letters on an eye chart a consumer should be able to see with that prescription. Professional Opticians of Florida (Comment #0803 submitted by Couch); Stuart (Comment #0841). The Commission also believes that whether such a measurement is required on a prescription should be determined by the states.

³⁹⁵ See Eyeglass Rule ANPR, 80 FR 53274, 53276.

eyeglasses may have evolved since that round of comments. Thus, it invites comments from any organizations or individuals who believe that, in analyzing this issue, the Commission should consider relevant changes to state regulations on the content of prescriptions, or to changes in the marketplace or to technology pertaining to pupillary distance, since it last sought comment.

B. Amending the Rule to Set an Expiration Date for Eyeglass Prescriptions

Although the 2015 ANPR for the Eyeglass Rule did not specifically request comment on the issue of expiration dates for eyeglass prescriptions, several commenters raised this topic. The Eyeglass Rule, as currently drafted, does not specifically address expiration dates for eyeglass prescriptions. Rather, the Rule defines an eyeglass prescription as the written specifications for lenses for eyeglasses, which are derived from an eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses.³⁹⁶ State laws determine whether a prescription must contain an expiration date, but these laws vary; some states require an expiration date on the prescription,³⁹⁷ others do not.³⁹⁸ Furthermore, to the extent state laws specify the length of time an eyeglass prescription is valid, these laws vary as well.³⁹⁹

³⁹⁶ 16 CFR 456.1(g).

³⁹⁷ Alaska Admin. Code 12 § 48.920; Cal. Bus. & Prof. Code § 2541.1; La. Admin. Code tit. 46, § LI-505; 246 Mass. Code Regs. 3.02; Miss. Code Ann. § 73-19-61; N.D. Admin. Code 56-02-04-03; 49 Pa. Code § 23.72.

³⁹⁸ Ark. Code Ann. § 17-90-108 (A)(3); Md. Code Ann. Health Occ. § 11-504.

³⁹⁹ Cal. Bus. & Prof. Code § 2541.1 (no less than two to four years from the date of issuance unless medical reason for shorter period); Fla. Stat. Ann. § 463.012 (expiration date of 5 years); Haw. Code R. § 16-92-2 (expiration date to be determined by licensed practitioner); Idaho Admin. Code R. § 24.10.450 (expiration date of at least one year); Iowa Admin. Code r. 645-182.3 (expiration date not to exceed two years); La. Admin. Code tit. 46, § LI-505 (expiration date may not exceed 18 months, unless medical reason); see also, D.C. Mun. Regs. tit. 17, § 6416.1 (expiration date of one year unless medical reason for shorter time period).

Some commenters suggested a variety of Rule amendments that would address the length of an eyeglass prescription, while other commenters expressed the view that the Commission should not amend the Rule to set expiration dates for eyeglass prescriptions. In advocating for an amendment to the Rule, some commenters expressed concern that since the expiration period for eyeglass prescriptions is not standardized, it allows some states “to impose arbitrary and, in some cases, unnecessarily short, expiration periods for prescriptions.”⁴⁰⁰ For example, Warby Parker commented that “many state laws allow ‘short-dated’ prescriptions, which force consumers to go back to their eye care professional each year if they want to obtain a valid prescription for new eyeglasses.”⁴⁰¹ Warby Parker argued that these provisions are without justification because the “vast majority of [eyeglass] prescriptions do not change within one year, and there is no medical rationale for most patients to undergo annual eye exams.”⁴⁰² U.S. Senator Charles Schumer requested that the Commission consider whether short-term prescriptions (for example, a year or less), are appropriate or fair for consumers given that vision does not necessarily change this rapidly.⁴⁰³ 1-800 CONTACTS concurred with this view, stating that allowing states to impose “arbitrary and, in some cases, unnecessarily short, expiration periods for prescriptions impairs the intent and effectiveness of the Eyeglass Rule and inhibits consumer’s ability to choose to obtain eyeglasses from third-party sellers.”⁴⁰⁴ 1-800 CONTACTS pointed out that, for this

⁴⁰⁰ 1-800 CONTACTS (Comment #0834 submitted by Williams); *see also* Warby Parker (Comment #0817 submitted by Kumar).

⁴⁰¹ Comment #0817 submitted by Kumar (citing as examples the state statutes of Iowa, Mississippi, and Pennsylvania, as well as the District of Columbia’s Eyeglass Rule).

⁴⁰² *Id.*

⁴⁰³ Comment #0865.

⁴⁰⁴ Comment #0834 submitted by Williams.

reason, the Contact Lens Rule includes a provision that addresses the expiration of contact lens prescriptions.⁴⁰⁵

1-800 CONTACTS therefore proposed that the Commission amend the Eyeglass Rule to include a provision imposing a minimum expiration period for prescriptions, with an exception for documented medical necessity, as there is in the CLR.⁴⁰⁶ Similarly, Warby Parker proposed that the Commission amend the Rule to adopt a three-year minimum prescription expiration timeframe, absent a documented medical basis for any particular short-dated prescription.⁴⁰⁷

Many consumers expressed frustration that eyeglass prescriptions expire too quickly and prevent them from purchasing new pairs of eyeglasses without undergoing another eye exam.⁴⁰⁸ For example, some commenters stated that their prescription rarely or never changes, but if they want new glasses or a second pair of glasses more than a year or two after their initial examination, a prescription expiration date may nonetheless

⁴⁰⁵ See 16 CFR 315.6 (setting a minimum expiration date of one year after the issue date of a prescription with an exception based on a patient's ocular health).

⁴⁰⁶ Comment #0834 submitted by Williams.

⁴⁰⁷ Comment #0817 submitted by Kumar; *see also* Buntain (Comment #0529) (amend the Rule to prohibit short-dated prescriptions without a medical necessity); Read (Comment #0741) (make prescriptions valid for three years).

⁴⁰⁸ See, e.g., Skidelsky (Comment #0085); Hendrick (Comment #0088); Loeb (Comment #0314); Bevington (Comment #0419); Gough (Comment #0422); Kinlaw (Comment #0424); Holden (Comment #0428); Steele (Comment #0432); Martin (Comment #0435); Miller (Comment #0437); Fernandez (Comment #0439); Washburn (Comment #0440); Birnbaum (Comment #0443); McLeod (Comment #0458); Kaminski (Comment #0462); Munkittrick (Comment #0465); Kaprielian (Comment #0488); Rouse (Comment #0496); Pearsall (Comment #0499); Simmons (Comment #0513); Iglinski (Comment #0516); Lauridsen (Comment #0526); Hamon (Comment #0537); Schutz (Comment #0549); Fair (Comment #0800); *see also* Garcia (Comment #0338) (Warby Parker employee reporting that consumers are unhappy with one-year expiration dates when their prescriptions have not changed); Beaudoin (Comment #0349) (same); Grecxo (Comment #0612) (Warby Parker optician reporting that expiration dates of less than two years make obtaining eyeglasses difficult and frustrating for some patients).

require them to return to the prescriber's office for a new eye examination.⁴⁰⁹ Some commenters discussed the costs associated with having to obtain another eye examination to get a prescription even though they were satisfied with their current prescription, or believed that their vision had not changed.⁴¹⁰ Other commenters argued that patients should be able to decide for themselves when they want to update their eyeglass prescriptions.⁴¹¹

Some commenters proposed that the Commission amend the Rule to prohibit eyeglass prescriptions from including an expiration date at all.⁴¹² For example, the Opticians Association of Virginia stated that absent a medical reason with corroborating pathology, it saw no valid reason for an eyeglass prescription to contain an expiration date.⁴¹³ This commenter argued that eyeglasses worn by the patient do not expire on a

⁴⁰⁹ See, e.g., Nystrom (Comment #0254); Hollis (Comment #0307); Trout (Comment #0383); Bhattacharyya (Comment #0543); Morel (Comment #0712).

⁴¹⁰ See, e.g., Sorenson (Comment #0080) (burden financially and time-wise to have to get re-examined every year); Kim (Comment #0192) (eye exams are expensive); Meszaros (Comment #0303) (one-year expiration dates increase annual costs without materially improving health care); Hollis (Comment #0526) (would like to see doctor less frequently); Gough (Comment #0422) (getting a new prescription not cheap); Holden (Comment #0428) (getting time off for an eye exam is difficult); Davis (Comment #0433) (have to pay for exam on top of the new eyeglasses); Martin (Comment #0435); Washburn (Comment #0440); Birnbaum (Comment #0443); Kaprielian (Comment #0488); Rouse (Comment #0496); Pearsall (Comment #0499); Buntain (Comment #0529); Buntain (Comment #0531) (prescriptions expire too soon and not everyone can afford to go to the doctor so often).

⁴¹¹ See, e.g., Hildenbrand (Comment #0049); Cordivari (Comment #0069); Sorenson (Comment #0080); Forrest (Comment #0270); Jump (Comment #0292); Loeb (Comment #0171); Richards (Comment #0401); Steele (Comment #0432); Davis (Comment #0433).

⁴¹² See, e.g., Forrest (Comment #0270) (prescriptions should not expire); Endelson (Comment #0407) (prescription should include date of examination but not an expiration date); Professional Opticians of Florida (Comment #0803 submitted by Couch) (recommending the prohibition of expiration dates on prescriptions for adult patients with low risk factors).

⁴¹³ Comment #0647 submitted by Nelms.

given date, and accordingly, there is no reason for the underlying prescription to expire.⁴¹⁴ The association further explained that because opticians can use a customer's existing pair of eyeglasses to ascertain the prescription parameters and make another pair using those parameters, from neutralizing or duplicating eyeglasses, expiration dates can be (and often are) circumvented.⁴¹⁵

However, other commenters, citing the importance of annual eye exams to consumers' eye health, stated that prescriptions should contain expiration dates, set at the discretion of the prescribing practitioner.⁴¹⁶ The AAO, and several other commenters, stated that the Rule should not be amended to extend the expiration of prescriptions beyond one year.⁴¹⁷ These commenters stressed the importance of yearly eye examinations, which function to monitor the health of the eye, and noted that patients' prescriptions often change. Many opticians, also advocating for yearly eye examinations, stated a preference for one-year expiration dates, but said that they would not be opposed to accepting prescriptions within a two-year period.⁴¹⁸ The AOA recommended that the

⁴¹⁴ *Id.*; *see also* Rhodes (Comment #0334) (one- or two-year expiration dates do not make sense and make it difficult to get replacement eyeglasses that one would otherwise be wearing but for losing them).

⁴¹⁵ Comment #0647 submitted by Nelms.

⁴¹⁶ Kalish (Comment #0048); Edwards (Comment #0360); Smith (Comment #0652); Lott (Comment #0655); Ambler (Comment #0025).

⁴¹⁷ Comment #0864 submitted by Haber; *see also* Adegbile (Comment #0004); Sung (Comment #0459); Jamison (Comment #0535); Moschell (Comment #0551); Shuler (Comment #0572); Cochrane (Comment #0583); Rozanec (Comment #0613); Leung (Comment #0623); Hicks (Comment #0624); Brosman (Comment #0637); Valentine (Comment #0644).

⁴¹⁸ Opticians Association of America (Comment #0638 submitted by Allen); Opticians Association of Kentucky (Comment #0640 submitted by Castle); Opticians Association of Vermont (Comment #0641 submitted by Williams); Opticians Alliance of New York (Comment #0642 submitted by Cullen); Ragan (Comment #0677); Opticians Association of Ohio (Comment #0683 submitted by Glasper); Parent (Comment #0693); Opticians Association of Iowa (Comment #0646 submitted by Dalton); Sasse (Comment

Commission not amend the Rule to address expiration dates, but rather continue to defer to state law and the medical judgment of optometrists and ophthalmologists as to when a prescription should expire.⁴¹⁹ The Rule's purpose is to allow consumers to comparison-shop for eyeglasses. In its comment, Warby Parker stated that short-term prescriptions require patients to return to the eye care prescriber more frequently, giving the prescriber additional opportunities to sell eyeglasses to patients.⁴²⁰ In support of this position, Warby Parker pointed to a handful of states that have enacted laws and regulations making the maximum effective date for prescription lenses one or two years. A review of various states' regulations on prescription expirations, however, indicates that many states do not regulate the length of eyeglass prescriptions.⁴²¹ Of the states that do regulate expiration dates, some set a floor for expiration, rather than a ceiling.⁴²² Of the states that do specifically limit the length of an eyeglass prescription, many set the expiration date at two or more years.⁴²³

Commenters seem to be arguing that expiration dates on prescriptions prevent consumers from continuing to purchase eyeglasses for a sufficiently long period before

#0733); Martin (Comment #0665); South Carolina Association of Opticians (Comment #0822 submitted by Harbert).

⁴¹⁹ Comment #0849 submitted by Peele.

⁴²⁰ Comment #0817 submitted by Kumar.

⁴²¹ See, e.g., Ark. Code Ann. § 17-90-108 (A)(3); Md. Code Ann., Health Occ. § 11-504; N.C. Gen. Stat. Ann. § 90-235; Utah Code Ann. § 58-16A-102 (prescription may include an expiration date).

⁴²² See Cal. Bus. & Prof. Code § 2541.1 (should not be less than 2-4 years); Idaho Admin. Code R. § 24.10.450 (must be at least one year); Wash. Rev. Code § 18.195.030 (at least two years).

⁴²³ Fla. Stat. Ann. § 463.012 (valid for a period of 5 years); Iowa Admin. Code. r. 645-182.3 (not to exceed two years); Me. Rev. Stat. tit. 34 A-2 § 2417 (not more than two years unless medical reason for a longer period); Nev. Rev. Stat. § 637.175 (two years unless specified otherwise by prescriber); N.H. Rev. Stat. Ann. § 327-A:1 (not more than 24 months); 49 Pa. Code § 23.72 (cannot exceed two years).

having to return to their eye doctors. The Commission lacks adequate evidence that eyeglass prescription expiration dates, whether imposed by state regulations or individual prescribers, impair comparison-shopping, and hence competition in the retail sale of eyeglasses, to an extent that would justify a new regulatory requirement.⁴²⁴

While requiring that consumers return to their prescriber periodically for exams may give the prescriber a competitive advantage in that they get a "first shot" at selling the consumers new eyeglasses, it does not necessarily limit the consumers' choices or ability to comparison-shop, particularly if the prescribers abide by the Rule's prescription release requirement. Absent evidence that expiration dates are impeding consumer choice, the Commission sees no support for the proposal that expiration dates need to be standardized.

Although some patients will not be able to purchase eyeglasses using a prescription more than one or two years old, this does not mean that they were foreclosed from comparison-shopping or from purchasing from the retailer of their choice when they initially purchased eyeglasses. Furthermore, as long as patients are provided a copy of the eyeglass prescription after the eye examination is completed, there is nothing in the record to support the contention that merely returning to a prescriber's office to obtain a new prescription will pressure the patient into purchasing from the prescriber. Accordingly, the Commission has determined not to propose to amend the Rule either to prohibit expiration dates or to set expiration dates for eyeglass prescriptions.⁴²⁵

⁴²⁴ In its comment to the current rule review, the AOA stated its belief that eye care practitioners do not use expiration dates to impede the ability of their patients to purchase eyeglasses from other retailers. Comment #0849 submitted by Peele.

⁴²⁵ In its 2004 review of the Eyeglass Rule, the Commission declined to consider amending the Rule to set expiration dates for eyeglass prescriptions. In that proceeding, the Opticians Association of America asked the Commission to amend the Rule to prohibit the use of expiration dates for eyeglass prescriptions, with exceptions for specific, well-defined medical reasons, arguing that practitioners used arbitrary and unjustifiable expiration dates to deter consumers from using their eyeglass prescriptions.

C. Amending Other Rule Definitions

The Rule defines an “eye examination” as “the process of determining the refractive condition of a person’s eyes or the presence of any visual anomaly by the use of objective or subjective tests.”⁴²⁶ The AOA and several individual prescribers requested that the Commission modify the Rule to change the term “eye examination” to “refraction.”⁴²⁷ These commenters stated that an eye examination determines the health of the eye and includes many components that are not used to determine the refractive condition. According to some commenters, the Rule’s definition for, and use of, the phrase “eye examination” more accurately describes refractive services rather than the full scope of an eye examination.⁴²⁸

Two commenters, in particular, noted that that eye examinations and refractions are separate services and that the Commission’s use of the terminology “eye examination,” instead of “refraction,” results in confusion for the consumer.⁴²⁹ Such confusion may stem from the fact that, in addition to assessing a fee for determining the health of the

Ophthalmic Practice Rules, 69 FR 5451, 5454. Because there was no evidence in that record that eye care prescribers were using expiration dates as a means of impeding consumers’ ability to purchase eyeglasses from other sellers or otherwise causing consumer injury, the Commission decided not to set expiration dates for eyeglass prescriptions. *Id.* Commission staff reached a similar conclusion in a prior Eyeglass Rule review, determining that prescription expiration duration should be left to the states. *See* 1980 Staff Report, *supra* note 25.

⁴²⁶ 16 CFR 456.1(b).

⁴²⁷ *See* AOA (Comment #0849 submitted by Peele); Brauer (Comment #0045); Yadon (Comment #0046; Bolenbaker (Comment #0633). Some of these commenters also stated that the defined term in the Rule is at odds with the definition of eye examination in the American Medical Association’s Current Procedural Terminology codes to bill outpatient and office procedures, because that definition does not include a refraction. AOA (Comment #0849 submitted by Peele); Bolenbaker (Comment #0633).

⁴²⁸ AOA (Comment #0849 submitted by Peele); Lunsford (Comment #0346); Bolenbaker (Comment #0633).

⁴²⁹ Lehman (Comment #0610); Bolenbaker (Comment #0633).

eye—a fee often covered by health insurance or Medicare—prescribers charge patients a fee for the refractive examination that results in a prescription, a fee that Medicare does not cover.⁴³⁰ The Rule currently allows eye care prescribers to refuse to provide the patient with their prescription when the patient has not paid for the “eye examination”—which refers back to the definition describing the refraction—as long as the prescriber does not have different policies for those whose examination revealed that no ophthalmic goods were required.⁴³¹

The Commission proposes to replace the term “eye examination” with “refractive eye examination” throughout the Rule. The Eyeglass Rule’s purpose is to ensure that prescribers provide patients with a copy of their prescription at the completion of an eye examination determining the patient’s refraction, and that this prescription be provided free of any additional charge, without obligation, and without a waiver. The Commission believes clarifying that the eye examination referred to in the Rule is a refractive examination would likely increase consumer understanding of their rights and prescriber compliance with the Rule.

VI. Recommendations Regarding the Commission’s Complaint System

To assist the Commission in its enforcement of the Rule, Warby Parker suggested that the Commission create a more “user-friendly” online complaint process for consumers.⁴³² The online complaint process has changed significantly since the receipt of this comment. The current website is user-friendly, and consumers can easily find eye

⁴³⁰ See Lehman (Comment #0610). Medicare does not cover refractive examinations for eyeglasses. See U.S. Centers for Medicare & Medicaid Services, “Your Medicare Coverage,” <https://www.medicare.gov/coverage/eye-exams.html>.

⁴³¹ The prescriber is permitted to withhold the prescription until the patient has paid for the eye examination, but only if that ophthalmologist or optometrist would have required immediate payment from that patient had the examination revealed that no ophthalmic goods were required. 16 CFR 456.2(a).

⁴³² Comment #0817 submitted by Kumar.

care as a category for their complaints.⁴³³ On the home page, one of the 10 listed complaint categories is for “health (ex. weight loss, eye care, treatment).” When consumers select the health category, a new menu pops up which shows “eye care” as one of five choices, and after selecting that category, consumers are given ample room to describe their experience in a comment box under the request to “Describe what happened.” Accordingly, the Commission believes that the FTC complaint system is well-configured to capture and report eyeglass-related complaints it receives, whether they originate from consumers, prescribers, sellers, or others.

VII. Request for Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Write “Eyeglass Rule, Project No. R511996” on the comment. Your comment—including your name and your state—will be placed on the <https://www.regulations.gov> website.

Because of public health measures and the agency’s heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comment online through the <https://www.regulations.gov> website. To ensure the Commission considers your online comment, please follow the instructions on the web-based form.

If you file your comment on paper, write “Eyeglass Rule, Project No. R511996” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex C), Washington, DC 20580.

Because your comment will be placed on the publicly accessible website

⁴³³ See www.reportfraud.ftc.gov.

<https://www.regulations.gov>, you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule § 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule § 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule § 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at www.regulations.gov—as legally required by FTC Rule § 4.9(b)—we cannot redact or remove your comment from the FTC Website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule § 4.9(c), and the General Counsel grants that request.

Visit the Commission website at <http://www.ftc.gov> to read this NPRM and the news release describing it. The FTC Act and other laws that the Commission administers

permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

The Commission invites members of the public to comment on any issues or concerns they believe are relevant or appropriate to the Commission's consideration of proposed amendments to the Rule. The Commission requests that you provide factual data, and in particular, empirical data, upon which your comments are based. In addition to the issues raised above, the Commission solicits public comment on the specific questions identified below. These questions are designed to assist the public and should not be construed as a limitation on the issues on which public comment may be submitted.

Questions

A. General Questions on Proposed Amendments: To maximize the benefits and minimize the costs for prescribers and sellers (including small businesses), the Commission seeks views and data on the following general questions for each of the proposed changes described in this NPRM:

1. What benefits would a proposed change confer and on whom? The Commission in particular seeks information on any benefits a change would confer on consumers of eyeglasses.
2. What costs or burdens would a proposed change impose and on whom? The Commission in particular seeks information on any burdens a change would impose on small businesses.
3. What regulatory alternatives to the proposed changes are available

that would reduce the burdens of the proposed changes while providing the same benefits?

4. What additional information, tools, or guidance might the Commission provide to assist industry in meeting extant or proposed requirements efficiently?

5. What evidence supports your answers?

B. Marketplace, Technological, and State Regulatory Changes:

1. Since the public last had an opportunity to comment, are there any technological changes, changes in the marketplace, or to state regulations pertaining to pupillary distance, that the Commission should consider?

C. Confirmation of Prescription Release:

1. Would the proposed Confirmation of Prescription Release provision increase, decrease, or have no effect on compliance with the Rule's requirement that patients receive a copy of their prescription after the completion of a refractive eye examination? Why?

2. Would the proposed requirement that prescribers would have to maintain evidence of the Confirmation of Prescription Release for at least three years increase, decrease, or have no effect on the Commission's ability to enforce, and monitor compliance with, the Rule's automatic prescription release provision? Why?

3. Would the proposed Confirmation of Prescription Release requirement increase, decrease, or have no effect on the extent to which patients understand their rights under the Rule? Why?

4. Does the proposal to allow prescribers to satisfy the Confirmation of Prescription Release requirement by releasing a digital copy of the prescription to the patient (after obtaining the patient's verifiable affirmative consent), such as

via online portal, electronic mail, or text message increase, decrease, or have no effect on the extent to which patients understand their rights under the Rule? Why?

5. If prescribers choose to comply with the Confirmation of Prescription Release provision by providing a digital copy of the prescription (if the patient gives verifiable affirmative consent), what costs or burdens are associated with retaining evidence that the prescription was sent, received, or made accessible, downloadable, and printable?

6. Do the potential benefits of the Confirmation of Prescription Release requirement—having more patients in possession of their prescription—outweigh the burden on prescribers of having to provide patients with a Confirmation of Prescription Release and preserve a record for three years? Why or why not?

7. What other factors should the Commission consider to lower the cost and improve the reliability of executing, storing, and retrieving Confirmations of Prescription Release?

8. Are there alternate ways that the Commission has not yet considered to design a Confirmation of Prescription Release requirement that would reduce the burden on prescribers while providing the same, or greater, benefits for consumers? What are they and how do they compare to the current proposal?

9. Are there alternate ways that the Commission has not yet considered in this Rule review to increase compliance with the Rule's requirement that patients receive a copy of their eyeglass prescription after the completion of a refractive eye examination? What are they and how do they compare to the current proposal?

10. Are there alternate ways that the Commission has not yet considered in its Rule review to increase the Commission's ability to enforce, and monitor compliance with, the Rule's automatic prescription release provision? What are they and how do they compare to the current proposal?

11. Are there alternate ways that the Commission has not yet considered in its Rule review to increase the extent to which patients understand their rights under the Rule? What are they and how do they compare to the current proposal?

12. Under the Commission's proposal, the Confirmation of Prescription Release requirement and the accompanying recordkeeping provision shall not apply to prescribers who do not have a direct or indirect financial interest in the sale of eyeglasses, including, but not limited to, through an association, affiliation, or co-location with a prescription-eyewear seller. Aside from associations, affiliations, and co-locations with prescription-eyewear sellers, what other indirect financial interests exist in the sale of prescription eyewear that should disqualify a prescriber from the proposed exemption?

13. Does the Contact Lens Rule's Confirmation of Prescription Release requirement reduce or increase the need for a similar requirement for the Eyeglass Rule?

14. What evidence supports your answers?

D. Electronic Delivery of Prescriptions:

1. The Commission believes that providing patients with a digital copy of their prescription, in lieu of a paper copy, would satisfy the automatic prescription release requirement (§ 456.2) if the patient gives verifiable affirmative consent and is able to access, download, and print the prescription. The Commission seeks comment on the benefits or the burdens that the option to

provide electronic delivery of prescriptions would confer.

2. Would prescribers choose to satisfy the automatic prescription release requirement through electronic delivery if permitted by the Rule?

3. Would a patient portal, email, or text message be feasible methods for prescribers to provide digital copies of prescriptions to patients? Are prescribers using any other electronic methods to provide patients with prescriptions?

4. What other technologies are available that could be implemented to improve prescription portability and thereby increase benefits and decrease burdens related to prescription release?

5. What evidence supports your answers?

E. Insurance as Payment

1. The Commission believes that it would be appropriate to amend the Eyeglass Rule to clarify that a patient's presentation of proof of insurance coverage shall be deemed to constitute a payment for purposes of determining when a prescription must be provided under 16 CFR 456.2(a). The Commission seeks comment on the benefits or the burdens that this clarification would confer.

2. Would clarifying that presentation of proof of insurance coverage shall be deemed to constitute a payment under § 456.2(a) increase, decrease, or have no effect on compliance with the Rule's requirement that patients receive a copy of their prescription after the completion of a refractive eye examination? Why?

3. Would clarifying that presentation of proof of insurance coverage shall be deemed to constitute a payment under § 456.2(a) increase, decrease, or have no effect on the Commission's ability to enforce, and monitor compliance with, the Rule's automatic prescription release provision? Why?

4. Would clarifying that presentation of proof of insurance coverage shall be deemed to constitute a payment under § 456.2(a) increase, decrease, or have no effect on the extent to which patients understand their rights under the Rule? Why?

5. What evidence supports your answers?

F. Eye Examination Term

1. Would changing the term “eye examination” throughout the Rule to “refractive eye examination” increase, decrease, or have no effect on compliance with the Rule’s requirement that patients receive a copy of their prescription after the completion of a refractive eye examination? Why?

2. Would changing the term “eye examination” throughout the Rule to “refractive eye examination” increase, decrease, or have no effect on the Commission’s ability to enforce, and monitor compliance with, the Rule’s automatic prescription release provision? Why?

3. Would changing the term “eye examination” throughout the Rule to “refractive eye examination” increase, decrease, or have no effect on the extent to which patients understand their rights under the Rule? Why?

4. Would using the term “refractive eye examination” in place of “eye examination” help avoid confusion over when the prescriber must release the prescription, and whether prescribers may withhold release of the prescription subject to any charges other than the one due for the refractive eye examination?

5. Is the current definition in the Rule, namely “the process of determining the refractive condition of a person’s eyes or the presence of any visual anomaly by the use of objective or subjective tests,” a clear and accurate way of describing a refractive eye examination?

6. Would using the term “refractive eye examination” in place of

“eye examination” have any other consequences for eye care, positive or negative?

7. What evidence supports your answers?

VIII. Communications by Outside Parties to the Commissioners or Their Advisors

Pursuant to FTC Rule § 1.18(c)(1)(i)-(ii), the Commission has determined that communications with respect to the merits of this proceeding from any outside party to any Commissioner or Commissioner advisor shall be subject to the following treatment. Written communications and summaries or transcripts of oral communications shall be placed on the rulemaking record if the communication is received before the end of the public comment period in response to this NPRM. They shall be placed on the public record if the communication is received later. Unless the outside party making an oral communication is a member of Congress, such communications are permitted only if advance notice is published in the Weekly Calendar and Notice of Sunshine Meetings.⁴³⁴

IX. Paperwork Reduction Act

The Paperwork Reduction Act (“PRA”), 44 U.S.C. 3501 et seq., requires federal agencies to obtain Office of Management and Budget (“OMB”) approval before undertaking a collection of information directed to ten or more persons. Pursuant to the regulations implementing the Paperwork Reduction Act,⁴³⁵ an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid OMB control number.

The Commission is proposing a number of modifications to the Rule that contain recordkeeping requirements that are collections of information as defined by OMB regulations that implement the PRA. First, the Commission is proposing to modify the

⁴³⁴ See 15 U.S.C. 57a(i)(2)(A); 16 CFR 1.18(c).

⁴³⁵ 5 CFR 1320.8(b)(2)(vi).

Rule to require that prescribers either: (i) obtain from patients, and maintain for a period of not less than three years, a signed confirmation of prescription release on a separate stand-alone document; (ii) obtain from patients, and maintain for a period of not less than three years, a patient's signature on a confirmation of prescription release included on a copy of a patient's prescription; (iii) obtain from patients, and maintain for a period of not less than three years, a patient's signature on a confirmation of prescription release included on a copy of a patient's refractive eye examination sales receipt; or (iv) provide each patient with a copy of the prescription via online portal, electronic mail, or text message, and for three years retain evidence that such prescription was sent, received, or made accessible, downloadable, and printable by the patient. For prescribers who choose to offer an electronic method of prescription delivery, the proposed Rule would require that such prescribers identify the specific method or methods to be used, and maintain records or evidence of affirmative consent by patients to such digital delivery for three years. For instances where a consumer refuses to sign the confirmation or accept digital delivery of their prescription, the proposed Rule directs the prescriber to note the refusal and preserve this record as evidence of compliance. None of the proposed new requirements, however, would apply to prescribers who do not have a direct or indirect financial interest in the sale of eyeglasses.

The Commission hereby provides PRA burden estimates, analysis, and discussion for the burden of automatically releasing a prescription at the completion of a refractive eye exam, as well as the proposed requirement to collect patient signatures as confirmation of prescription release and as consent to electronic prescription delivery. Commission staff estimates these PRA burdens based on its long-standing knowledge

and experience with the eye care industry.⁴³⁶ The Commission is submitting these proposed amendments and a Supporting Statement to OMB for review.

A. Estimated Burden

The number of adult eyeglass wearers in the United States is currently estimated to be approximately 165 million.⁴³⁷ Assuming a biennial refractive eyeglass exam for each eyeglass wearer,⁴³⁸ approximately 82.5 million people would receive a copy of their eyeglass prescription every year. Historically, the Commission has estimated that it takes one minute to provide the patient with a prescription copy, and that it is the prescriber, and not the prescriber's office staff, that provides the prescription to the consumer.⁴³⁹ We therefore estimate an annual disclosure burden for prescribers of approximately 1,375,000 hours (82.5 million annual exams \times 1 min/60 mins).

⁴³⁶ See Section I.B, *supra*.

⁴³⁷ See VisionWatch Report, *supra* note 70, at 24.

⁴³⁸ The Commission relies on industry sources for its estimate that eyeglass wearers typically obtain one refractive eye exam every two years. See, e.g., AOA, Excel and Jobson Medical Information, The State of the Optometric Profession: 2013, at 4, <https://www.reviewob.com/wp-content/uploads/2016/11/8-21-13stateofoptometryreport.pdf> (showing an average interval between exams of 25 months); AOA, Comprehensive Eye Exams, <https://www.aoa.org/healthy-eyes/caring-for-your-eyes/eye-exams?sso=y> (showing recommended examination frequency for adult patients 18-64 of "at least every two years" for asymptomatic/low risk patients). In contrast to the CLR, which establishes a one-year minimum term for most contact lens prescriptions (16 CFR 315.6(a)) (a term-length mirrored by a majority of states, see CLR NPRM, 81 FR 88526, 88545, n.245), the Eyeglass Rule does not discuss or define prescription expiration terms, and many states do not set any limit for eyeglass prescriptions. See note 399, *supra* (summarizing a number of state laws that allow eyeglass prescriptions to be valid for periods longer than one year). Some eyeglass wearers, therefore, can legally go many years between refractive eye examinations. But the Commission will use two years as a basis for purposes of this assessment, since that is recommended interval for the majority of eyeglass wearers.

⁴³⁹ It is quite possible that one minute is an overestimate of the amount of time required, and that in practice, this task takes less time and is often performed by office staff rather than the prescriber. As of now, however, we have not seen conclusive evidence to justify making a change to the approach we have repeatedly taken in the past. See, e.g., CLR SNPRM, 84 FR 24664, 24693 n.347.

Staff anticipates there will be an additional burden on individual prescribers' offices to maintain signed confirmation forms for a period of not less than three years, but believes the overall burden imposed by the Rule remains relatively small in the context of the overall market for eyeglasses and refractive examinations. Based on the Commission's assumption of the number of refractive eye examinations that occur annually, staff estimates that 82.5 million people would either read and sign a confirmation of prescription release, or sign a confirmation agreeing to receive their prescription electronically every year.

The Commission believes that generating and presenting the confirmation of prescription release will not require significant time or effort. The proposed requirement is flexible in that it allows any one of several different modalities and delivery methods, including adding the confirmation to existing documentation that prescribers routinely provide (sales receipts) or are already required to provide (prescriptions) to patients. The proposed requirement is also flexible in that it does not prescribe other details, such as the precise content or language of the patient confirmation, but merely requires that, if provided to the patient pursuant to options specified in § 456.3(a)(1), the confirmation from the patient must be in writing. At the same time, prescribers would not have to spend time formulating their own content for the confirmation, since the proposed Rule provides draft language that prescribers are free to use, should they so desire.

The four options for a prescriber to confirm a prescription release to a patient are set out in proposed § 456.3(a)(1)(i), (ii), (iii), and (iv). The requirement in options § 456.3(a)(1)(i), (ii), and (iii) to provide the patient with a confirmation of prescription release are not disclosures constituting an information collection under the PRA because the FTC, in § 456.3(a)(2), has supplied the prescriber with draft language the prescriber

can use to satisfy this requirement.⁴⁴⁰ As noted above, however, the requirement in (i), (ii), and (iii) to collect a patient's signature on the confirmation of prescription release and preserve it constitutes an information collection as defined by OMB regulations that implement the PRA. Nonetheless, the Commission believes it will require minimal time for a patient to read the confirmation and provide a signature. The Commission estimated in the Contact Lens Rule that it would take patients ten seconds to read the one-sentence confirmation of prescription release and provide a signature,⁴⁴¹ and the Commission believes that ten seconds is an appropriate estimate for the Eyeglass Rule confirmation as well.

The fourth proposed option, § 456.3(a)(1)(iv), does not, in and of itself, constitute an information collection under the PRA, since no new information that would not otherwise be provided under the Rule is provided to or requested from the patient.⁴⁴² Excluding that option from consideration, and assuming the remaining three options are exercised with equal frequency, 75% of approximately 82.5 million annual prescription releases will entail reading and signing a confirmation statement. Thus, assuming ten seconds for each release, prescribers would devote 171,875 hours, cumulatively ($75\% \times$

⁴⁴⁰ "The public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not included within" the definition of "collection of information." 5 CFR 1320.3(c)(2). It is also notable that for the options in proposed §§ 456.3(a)(1)(ii) and (iii), the confirmation information would be printed on the same document—the prescription copy or sales receipt—that the prescriber would ordinarily provide to the consumer in any event.

⁴⁴¹ CLR Final Rule, 85 FR 50668, 50709. This estimate was based on responses to a consumer survey regarding how long it would take consumers to read the form, and a prior PRA estimate for consumers to complete a similar signed acknowledgment. *See* CLR SNPRM, 84 FR 24664, 24693.

⁴⁴² In order to utilize § 456.3(a)(1)(iv), however, a prescriber must obtain and maintain records or evidence of affirmative consent by patients to electronic delivery of their prescriptions. 16 CFR 456.1(h)(2). The burden to do so is included in the recordkeeping burden calculation of this PRA Section.

82.5 million prescriptions yearly \times 10 seconds each/60secs/60mins) to obtaining patient signatures as confirmations of prescription release.⁴⁴³

Maintaining those signed confirmations for a period of not less than three years should also not impose substantial new burdens on individual prescribers and office staff. The majority of states already require that optometrists keep records of eye examinations for at least three years,⁴⁴⁴ and thus many prescribers who opt to include the confirmation of prescription release on the prescription itself would be preserving that document, regardless. Similarly, most prescribers already retain customer sales receipts for financial accounting and recordkeeping purposes, and thus prescribers who opt to include the confirmation of prescription release on the sales receipt also could be retaining that document, regardless. Moreover, storing a one-page document per patient per year should not require more than a few seconds, and an inconsequential, or *de minimis*, amount of record space. Some prescribers might also present the confirmation of prescription release in electronic form, enabling patients to sign a computer screen or tablet directly, and have their confirmation immediately stored as an electronic document.

For other prescribers, the proposed recordkeeping requirement would likely require that office staff either preserve the confirmation in paper format, or electronically scan the signed confirmation and save it as an electronic document. For prescribers who preserve the confirmation electronically by scanning it, Commission staff estimates that

⁴⁴³ Section 456.3(a)(3) also requires that in the event that a patient declines to sign a confirmation requested under paragraphs (a)(1)(i), (ii), or (iii), the prescriber must note the patient's refusal on the document and sign it. However, the Commission has no reason to believe that such notation should take any longer than for the patient to read and sign the document, so the Commission will maintain its calculation as if all confirmations requested under (a)(1)(i), (ii), or (iii) require the same amount of time.

⁴⁴⁴ See, e.g., 246 Mass. Code Regs. § 3.02 (requiring optometrists to maintain patient records for at least seven years); Wash. Admin. Code § 246-851-290 (requiring optometrists to maintain records of eye exams and prescriptions for at least five years); Iowa Admin. Code r. 645-182.2(2) (requiring optometrists to maintain patient records for at least five years).

saving such a document would consume approximately one minute of staff time. Commission staff does not possess detailed information on the percentage of prescribers' offices that currently use and maintain paper forms or electronic forms, or that scan paper files and maintain them electronically. Thus, for purposes of this PRA analysis, Commission staff will assume that *all* prescriber offices who opt for § 456.3(a)(1)(i), (ii), or (iii) require a full minute per confirmation for recordkeeping arising from the modifications. Excluding from PRA consideration the fourth option, § 456.3(a)(1)(iv), as there is no signature to obtain or retain, and assuming that prescribers elect the other options three-fourths or 75% of the time, the recordkeeping burden for all prescribers' offices to scan and save such confirmations would amount to 1,031,250 hours (75% × 82.5 million prescriptions yearly × one minute for scanning and storing/60mins) per year.

As noted previously, the fourth option for satisfying the confirmation of prescription release requirement does not necessitate that prescribers obtain or maintain a record of the patient's signature confirming receipt of her prescription. However, as explained in § 456.1(h)(2), under the Rule's new proposed definition of *Provide to the patient one copy*, in order to avail themselves of the fourth option, prescribers must obtain and maintain records or evidence of the patients' affirmative consent to electronic delivery for three years. The Commission will use the assumption that consumers sign such consents for electronic delivery pursuant to § 456.3(a)(1)(iv), for one quarter of the 82.5 million prescriptions released per year,⁴⁴⁵ and that this task would take the same amount of time as to obtain and maintain a signature of the patient's confirmation of prescription release. Thus, the Commission will allot 401,042 hours⁴⁴⁶ for the time

⁴⁴⁵ 20,625,000 prescriptions (82.5 million prescriptions × 25%).

⁴⁴⁶ 57,292 hours (20,625,000 prescriptions yearly × 10 seconds/60secs/60mins) for obtaining the signature plus 343,750 hours (20,625,000 affirmative consents × one minute/60mins) for storing such records.

required for prescribers to obtain patients' affirmative consent to electronic delivery of their prescriptions and maintain records of same.

Therefore, the estimated incremental PRA recordkeeping burden for prescribers and their staff resulting from the confirmation of prescription release modifications to the Rule amounts to 1,604,167 total hours (171,875 and 57,292 hours, respectively, to obtain signatures confirming release and consenting to electronic delivery, plus 1,031,250 and 343,750 hours, respectively, to maintain records of confirmation and consent for three years). Adding the estimated incremental PRA recordkeeping burden for prescribers and their staff from the confirmation of prescription release proposal to the burden from the requirement that prescribers provide patients with copies of their prescriptions yields a total disclosure and recordkeeping burden from the Rule of 2,979,167 hours for prescribers and their staff (1,375,000 disclosure hours + 1,604,167 recordkeeping hours).

B. Estimated Labor Cost

Commission staff derives labor costs by applying appropriate hourly-cost figures to the burden hours described above. The task to obtain patient confirmations and consent to electronic delivery could theoretically be performed by medical professionals (*e.g.*, optometrists, ophthalmologists) or their support staff (*e.g.*, dispensing opticians, medical technicians, office clerks). In its Contact Lens Rule review, the Commission requested comment as to whether prescribers or office staff are more likely to collect patient signatures and retain associated recordkeeping, but did not receive significant guidance on this.⁴⁴⁷ Therefore, the Commission will continue to assume that optometrists will perform the task of collecting patient signatures, and that prescribers' office staff will perform the labor pertaining to printing, scanning, and storing of documents, even though

⁴⁴⁷ CLR Final Rule, 85 FR 50668, 50710.

these assumptions may lead to some overcounting of the burden (if, in actuality, prescribers' office staff obtain patient signatures).

According to the U.S. Bureau of Labor Statistics, salaried optometrists earn an average wage of \$60.31 per hour, and general office clerks earn an average wage of \$18.75 per hour.⁴⁴⁸ Using the aforementioned estimate of 229,167 total prescriber labor hours for obtaining patient signatures, the resultant aggregate labor costs to obtain patient signatures is \$13,821,062 (229,167 hours × \$60.31). Applying a mean hourly wage for office clerks of \$18.75 per hour to the aforementioned estimate of 1,375,000 hours for printing, scanning and storing of prescription release confirmations and consent agreements, labor costs for those tasks would total \$25,781,250. Therefore, combining the aggregate labor costs for both prescribers and office staff to obtain signed patient confirmations and consent to electronic delivery and preserve the associated records, the Commission estimates the total annual labor burden of the confirmation of prescription release modification to be \$39,602,312.

Adding the \$39,602,312 burden from the confirmation of prescription release requirement to the \$82,926,250 burden⁴⁴⁹ from the prescription release requirement already in place yields a total estimated annual labor cost burden for the Eyeglass Rule of \$122,528,562. While not insubstantial, this amount constitutes approximately one half of one percent of the estimated overall retail market for eyeglass sales in the United States.⁴⁵⁰ Furthermore, the actual burden is likely to be less, because many prescribers' offices will require less than a minute to store the confirmation form.

⁴⁴⁸ Bureau of Labor Statistics, United States Department of Labor, Occupational Employment Statistics, <https://www.bls.gov/news.release/ocwage.t01.htm>.

⁴⁴⁹ 1,375,000 hours × \$60.31 (average hourly wage for optometrists) = \$82,926,250.

⁴⁵⁰ According to The Vision Council, the eyeglass market (for frames and lenses) in the United States for the twelve months ending December 2019, totaled roughly \$24.3

C. Capital and Other Non-Labor Costs

The proposed recordkeeping requirements detailed above regarding prescribers impose negligible capital or other non-labor costs, as prescribers likely have already the necessary equipment and supplies (e.g., prescription pads, patients' medical charts, scanning devices, recordkeeping storage) to perform those requirements.

The Commission invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the FTC's burden estimates, including whether the methodology and assumptions used are valid; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of collecting information.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this document to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The [reginfo.gov](http://www.reginfo.gov) web link is a United States Government website produced by OMB and the General Services Administration ("GSA"). Under PRA requirements, OMB's Office of Information and Regulatory Affairs reviews federal information collections.

X. Preliminary Regulatory Analysis and Regulatory Flexibility Act Requirements

Under section 22 of the FTC Act, 15 U.S.C. 57b-3, the Commission must issue a preliminary regulatory analysis for a proceeding to amend a rule only when it: (1) estimates that the amendment will have an annual effect on the national economy of

billion. *See* VisionWatch Report, *supra* note 70, at 69, 89; Vision Council, "Consumer Barometer," Dec. 2019, at 18-19. The estimated total burden of the Rule of \$122,528,562 thus amounts to approximately 0.5 percent of the total market.

\$100,000,000 or more; (2) estimates that the amendment will cause a substantial change in the cost or price of certain categories of goods or services; or (3) otherwise determines that the amendment will have a significant effect upon covered entities or upon consumers. For the reasons explained below, in the PRA section above, and in the main text of this document, the Commission has preliminarily determined that the proposed amendments will not have such effects on the national economy; on the cost of eye examinations or prescription eyeglasses; or on covered parties or consumers. The Commission, however, requests comment on the economic effects of the proposed amendments.

The Regulatory Flexibility Act (“RFA”), 5 U.S.C. 601 et seq., requires the Commission to conduct an analysis of the anticipated economic impact of the proposed amendments on small entities. The purpose of a regulatory flexibility analysis is to ensure the agency considers the impacts on small entities and examines alternatives that could achieve the regulatory purpose while minimizing burdens on small entities. Section 605 of the RFA provides that such an analysis is not required if the agency head certifies that the regulatory action will not have a significant economic impact on a substantial number of small entities.

The Commission does not anticipate that the proposed amendments will have a significant economic impact on small entities, although they may affect a substantial number of small businesses. The proposed amendments would require that prescribers obtain from patients, and maintain for a period of not less than three years, a signed confirmation of prescription release, acknowledging that patients received their eyeglass prescriptions at the completion of their refractive eye examination. The new proposals would also require some prescribers to obtain and maintain for three years a patient’s consent to deliver prescriptions electronically, but only for prescribers who elect to offer this method of delivery as an alternative to providing prescriptions in paper, and only if

the patient agrees.

As described in the PRA section of this document, the Commission approximates that collecting a patient's signature on the confirmation of prescription release (giving time for patient to read confirmation) in accordance with § 456.3(a)(1)(i), (ii), and (iii) will take approximately ten seconds. Providing the patient with the confirmation of prescription release in accordance with this provision will require prescribers' offices to present a form, receipt, or prescription and request a patient signature. The proposed amendments to the Rule provide prescribers with the language that they can use on a confirmation form, which will relieve prescribers of that burden, and a request to sign such confirmation will take a *de minimis* amount of time. This requirement may also involve some staff training, which the Commission believes will be minimal. As a result, the Commission believes that complying with § 456.3(a)(1)(i), (ii), and (iii)) will impose only minimal costs upon prescriber offices, but requests information about the associated costs and burdens.

The PRA section of this document addresses the burden for prescribers to maintain records of confirmation of receipt of prescriptions for at least three years, noting that the majority of states already require that optometrists keep records of eye examinations for at least three years, and estimating a full minute for prescribers to meet their recordkeeping obligations. Prescribers who decide to collect or maintain signatures electronically may already have electronic health records systems in place, but the Commission requests information on costs prescribers are likely to incur to comply with the recordkeeping proposals in this document.

In addition, the proposal to permit prescribers to deliver prescriptions electronically would require prescribers to obtain, and maintain for three years, a patient's consent to electronic prescription delivery. This requirement can be avoided altogether should a prescriber not wish to provide patients this option. Furthermore,

whenever a prescriber enables a patient to receive a prescription electronically, this relieves the prescriber of the burden to obtain a signed prescription release confirmation from that patient. However, as explained in § 456.1(h)(2), under the Rule's new definition of *Provide to the patient one copy*, to avail themselves of the fourth option, prescribers must obtain and maintain records or evidence of the patients' affirmative consent to electronic delivery for three years. The PRA section of this document assumed that this task would take one minute and ten seconds, the same amount of time as to obtain and maintain a signature of the patient's confirmation of prescription release. The Commission requests information on costs that may be incurred by prescribers to comply with this option for prescription delivery.

Although the proposed amendments will impose a small burden upon prescribers, the proposed amendments should not have a significant or disproportionate impact on prescribers' costs. Therefore, based on available information, the Commission certifies that amending the Rule as proposed will not have a significant economic impact on a substantial number of small businesses.

Although the Commission certifies under the RFA that the proposed amendments, if promulgated, will not have a significant impact on a substantial number of small entities, the Commission has nonetheless determined it is appropriate to publish an Initial Regulatory Flexibility Analysis to inquire into the impact of the proposed amendments on small entities. Therefore, the Commission has prepared the following analysis:

B. Description of the Reasons the Agency Is Taking Action

In response to public comments, the Commission proposes amending the Rule to ensure that patients are receiving a copy of their eyeglass prescription at the completion of a refractive eye examination.

C. Statement of the Objectives of, and Legal Basis for, the Proposed Amendments

The objective of the proposed amendments is to clarify and update the Rule in

accordance with marketplace practices. The Commission promulgated the Rule pursuant to section 18 of the FTC Act, 15 U.S.C. 57a. As noted earlier, the Commission has wide latitude in fashioning a remedy and need only show a “reasonable relationship” between the unfair or deceptive act at issue and the remedy.⁴⁵¹ The proposed amendments to the Rule requiring that prescribers obtain from patients, and maintain for a period of not less than three years, a signed confirmation of patients’ receipt of their eyeglass prescriptions, permitting prescribers to comply with automatic prescription release via electronic delivery in certain circumstances, clarifying that the presentation of proof of insurance coverage shall be deemed to be a payment for the purpose of determining when a prescription must be provided under 16 CFR 456.2(a), and replacing the term “eye examination” with “refractive eye examination,” are reasonably related to remedying the unfair practices that led the Commission to promulgate the Rule.

D. Small Entities to Which the Proposed Amendments Will Apply

The proposed amendments apply to prescribers of eyeglasses. The Commission believes that many prescribers will fall into the category of small entities (*e.g.*, offices of optometrists less than \$8 million in size).⁴⁵² Determining a precise estimate of the number of small entities covered by the Rule’s prescription release requirements is not readily feasible because most prescribers’ offices do not release the underlying revenue information necessary to make this determination.⁴⁵³ Based on its knowledge of the eye care industry, including meetings with industry members and a review of industry publications, staff believes that a substantial number of these entities likely qualify as

⁴⁵¹ *Am. Fin. Servs. Ass’n v. FTC*, 767 F.2d at 988 (quoting *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612-13 (1946)).

⁴⁵² *See* 13 CFR 121.201 (Small Business Size Regulations).

⁴⁵³ 5 U.S.C. 601(6).

small businesses.⁴⁵⁴ The Commission seeks comment with regard to the estimated number or nature of small business entities, if any, for which the proposed amendments would have a significant impact.

E. Projected Reporting, Recordkeeping, and Other Compliance Requirements, Including Classes of Covered Small Entities and Professional Skills Needed to Comply

As explained earlier in this document, the proposed amendments require that prescribers obtain from patients, and maintain for a period of not less than three years (in paper or electronic form), a signed confirmation of prescription release, acknowledging that patients received their eyeglass prescriptions at the completion of their refractive eye examination. The amendments also permit prescribers to comply with automatic prescription release via electronic delivery in certain circumstances, clarify that the presentation of proof of insurance coverage shall be deemed to be a payment for the purpose of determining when a prescription must be provided under 16 CFR 456.2(a), and replace the term “eye examination” with “refractive eye examination” throughout the Rule.

The small entities potentially covered by these proposed amendments will include all such entities subject to the Rule. The professional skills necessary for compliance with the Rule as modified by the proposed amendments will include office and administrative support supervisors to create the confirmation form and clerical personnel to collect signatures from patients and maintain records. Compliance may include some minimal

⁴⁵⁴ According to one publication, 65 percent of optometrists work in a practice owned by an optometrist or ophthalmologist, practices that are likely small businesses. See AOA, “An Action-Oriented Analysis of the State of the Optometric Profession: 2013,” at 7, https://documents.aoa.org/Documents/news/state_of_optometry.pdf. This publication also reported that although it could not ascertain the precise number of independent optometric practices, it estimated that as of 2012, there were 14,000 to 16,000 optometric businesses with no corporate or institutional affiliation. *Id.*

training time as well.⁴⁵⁵ The Commission believes the burden imposed on small businesses by these requirements is relatively small, for the reasons described previously in this section as well as the PRA section of this document. The Commission invites comment and information on these issues, including estimates or data on specific compliance costs that small entities might be expected to incur.

F. Duplicative, Overlapping, or Conflicting Federal Rules

The Commission has not identified any other federal statutes, rules, or policies duplicating, overlapping, or conflicting with the proposed amendments. As noted previously, the majority of states already require that optometrists—of which many are most likely small businesses—maintain records of eye examinations for at least three years. Further, as discussed elsewhere in this NPRM, HIPAA, the 21st Century Cures Act, and state laws provide consumers with a right of access to medical records, though the parameters and timing involved with access are different than the Eyeglass Rule.⁴⁵⁶ The Commission also notes that prescribers may reduce any burden associated with the proposed amendments by using the same mechanism to obtain confirmation of receipt of a contact lens prescription (in accordance with the Contact Lens Rule) and an eyeglass prescription in cases when the prescriber provides both prescriptions to the patient at the same time, so long as the prescriber asks for separate signatures for each. The Commission invites additional comment on the issue of duplicative, overlapping or

⁴⁵⁵ The Commission does not believe it will require significant training to learn when and how to obtain a patient signature and preserve it, particularly since prescribers' office staff will already know how to perform these tasks, due to similar signature requirements already in place for the Contact Lens Rule and the HIPAA NPP, among others.

⁴⁵⁶ Prescribers may have EHRs in place to comply with these laws, as well as having certified health information technology to receive direct payments per the HITECH Act. The fact that prescribers' offices have EHRs and health information technology may make it less costly or burdensome for prescribers to comply with the proposed amendments to the Eyeglass Rule.

conflicting federal rules.

G. Significant Alternatives to the Proposed Amendments

The Commission has not proposed any specific small entity exemption or other significant alternatives, as the proposed amendments clarify and update the Rule in light of marketplace practices to ensure that patients are receiving a copy of their eyeglass prescription at the completion of a refractive eye examination. Under these limited circumstances, the Commission does not believe a special exemption for small entities or significant compliance alternatives are necessary or appropriate to minimize the compliance burden, if any, on small entities while achieving the intended purposes of the proposed amendments. As discussed above, the proposed recordkeeping requirement likely involves minimal burden and prescribers would be permitted to maintain records in either paper or electronic format. This recordkeeping burden could be reduced to the extent that prescribers have adopted electronic medical record systems, especially those where patient signatures can be recorded electronically and inputted automatically into the electronic record. Furthermore, prescribers also could scan signed paper copies of the confirmation and store those confirmations electronically to lower the costs of this recordkeeping requirement. Similarly, when using a text message, electronic mail, or an online patient portal to satisfy the prescription release requirement (assuming the patient's consent), prescribers may provide the required copy of the prescription electronically (i.e., digital format). Nonetheless, the Commission seeks comment on the need, if any, for alternative compliance methods to reduce the economic impact of the Rule on small entities. If the comments filed in response to this NPRM identify small entities affected by the proposed amendments, as well as alternative methods of compliance that would reduce the economic impact of the proposed amendments on such entities, the Commission will consider the feasibility of such alternatives and determine whether they should be incorporated into the final rule.

Proposed Rule Language

List of Subjects in 16 CFR Part 456

Advertising, Medical devices, Ophthalmic goods and services, Trade practices.

For the reasons set out in the preamble, the Federal Trade Commission proposes to amend 16 CFR part 456 to read as follows:

PART 456—OPHTHALMIC PRACTICE RULES (EYEGLOSS RULE)

1. Revise the authority citation for part 456 to read as follows:

Authority: 15 U.S.C. 57a.

2. Amend § 456.1 by revising paragraphs (a), (b), (d), (e) and (g), and by adding paragraph (h) to read as follows:

§ 456.1 Definitions.

(a) A *patient* is any person who has had a refractive eye examination.

(b) A *refractive eye examination* is the process of determining the refractive condition of a person's eyes or the presence of any visual anomaly by the use of objective or subjective tests.

* * * * *

(d) *Ophthalmic services* are the measuring, fitting, and adjusting of ophthalmic goods subsequent to a refractive eye examination.

(e) An *ophthalmologist* is any Doctor of Medicine or Osteopathy who performs refractive eye examinations.

* * * * *

(g) A *prescription* is the written specifications for lenses for eyeglasses which are derived from a refractive eye examination, including all of the information specified by state law, if any, necessary to obtain lenses for eyeglasses.

(h) *Provide to the patient one copy* means giving a patient a copy of his or her prescription:

(1) On paper; or

(2) In a digital format that can be accessed, downloaded, and printed by the patient. For a copy provided in a digital format, the prescriber shall identify to the patient the specific method or methods of electronic delivery to be used, such as text message, electronic mail, or an online patient portal, and obtain the patient's verifiable affirmative consent to receive a digital copy through the identified method or methods; and maintain records or evidence of a patient's affirmative consent for a period of not less than three years. Such records or evidence shall be available for inspection by the Federal Trade Commission, its employees, and its representatives.

3. Revise § 456.2 to read as follows:

§ 456.2 Separation of examination and dispensing.

It is an unfair act or practice for an ophthalmologist or optometrist to:

- (a) Fail to provide to the patient one copy of the patient's prescription immediately after the refractive eye examination is completed. Provided: An ophthalmologist or optometrist may refuse to give the patient a copy of the patient's prescription until the patient has paid for the refractive eye examination, but only if that ophthalmologist or optometrist would have required immediate payment from that patient had the examination revealed that no ophthalmic goods were required. For purposes of the preceding sentence, the presentation of proof of insurance coverage for that service shall be deemed to be a payment;
- (b) Condition the availability of a refractive eye examination to any person on a requirement that the patient agree to purchase any ophthalmic goods from the ophthalmologist or optometrist;
- (c) Charge the patient any fee in addition to the ophthalmologist's or optometrist's refractive eye examination fee as a condition to releasing the prescription to the patient.

Provided: An ophthalmologist or optometrist may charge an additional fee for verifying ophthalmic goods dispensed by another seller when the additional fee is imposed at the time the verification is performed; or

(d) Place on the prescription, or require the patient to sign, or deliver to the patient a form or notice waiving or disclaiming the liability or responsibility of the ophthalmologist or optometrist for the accuracy of the refractive eye examination or the accuracy of the ophthalmic goods and services dispensed by another seller.

4. Revise § 456.3 to read as follows:

§ 456.3 Confirmation of prescription release.

(a)(1) Upon completion of a refractive eye examination, and after providing a copy of the prescription to the patient, the prescriber shall do one of the following:

(i) Request that the patient acknowledge receipt of the prescription by signing a separate statement confirming receipt of the prescription;

(ii) Request that the patient sign a prescriber-retained copy of the prescription that contains a statement confirming receipt of the prescription;

(iii) Request that the patient sign a prescriber-retained copy of the sales receipt for the refractive eye examination that contains a statement confirming receipt of the prescription; or

(iv) If a digital copy of the prescription was provided to the patient (via methods including an online portal, electronic mail, or text message), retain evidence that such prescription was sent, received, or made accessible, downloadable, and printable.

(2) If the prescriber elects to confirm prescription release via paragraphs (a)(1)(i), (ii), or (iii) of this section, the prescriber may, but is not required to, use the statement, "My eye care professional provided me with a copy of my prescription at the completion of my examination" to satisfy the requirement.

(3) In the event the patient declines to sign a confirmation requested under paragraphs (a)(1)(i), (ii), or (iii) of this section, the prescriber shall note the patient's refusal on the document and sign it.

(b) A prescriber shall maintain the records or evidence required under paragraph (a) of this section for a period of not less than three years. Such records or evidence shall be available for inspection by the Federal Trade Commission, its employees, and its representatives.

(c) Paragraphs (a) and (b) of this section shall not apply to prescribers who do not have a direct or indirect financial interest in the sale of eye wear, including, but not limited to, through an association, affiliation, or co-location with an optical dispenser.

§ § 456.3 through 456.5 [Redesignated]

5. Redesignate §§ 456.3 through 456.5 as §§ 456.4 through 456.6.

§ 456.3 [Reserved]

6. Add and reserve a new § 456.3.

By direction of the Commission.

April J. Tabor,

Secretary.